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Congress of the United States
Office of Technology Assessment

LIFE-SUSTAINING TECHNOLOGIES AND THE ELDERLY
WORKING PAPERS, VOLUME 1: THE TECHNOLOGIES, PART 1

July, 1987

Cardiopulmonary Resuscitation in the Elderly, by Christine K. Cassel, Marc D. Silverstein, John LaPuma, Michael McCally, Dianne Roland, Mary Ahern, and Suzanne Mitchell, Center for Clinical Medical Ethics, Pritzker School of Medicine, University of Chicago, Chicago, IL.

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Hemodialysis, Peritoneal Dialysis, and Related Therapies for Renal Dialysis and the Elderly/Technology, by Christopher R. Blagg, Northwest Kidney Center, Seattle, WA.

Renal Dialysis Decisionmaking, by Richard B. Freeman, University of Rochester Medical Center, Rochester, NY.

Report on the Treatment of Elderly Patients by Dialysis and Transplantation in Europe, by S. Challah, European Dialysis and Transplant Association, London, U.K.

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**Cardiopulmonary Resuscitation
in the Elderly**

**A Contract for the U.S. Congress
Office of Technology Assessment
Project on**

Life-Sustaining Technologies in the Elderly

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INTRODUCTION

Cardiopulmonary resuscitation (CPR) is a definitive, highly developed technology for re-establishing heartbeat and respiration. Approximately 2 million people die each year in the United States, and potentially all could be recipients of CPR. Only 20 percent of those 2 million die outside of health care institutions where the technology and know how are available, but many communities are providing lay education in CPR so that a bystander can attempt resuscitation if someone collapses on the street. It is not appropriate, however, nor is it the case, that a resuscitation attempt is made in every instance of cardiac or respiratory arrest. There are simply times when response is impossible, but there are also occasions when it is not ethically indicated. There are few absolute criteria to discern this latter category, however, because outcomes almost always have some degree of uncertainty. As people age, and are therefore actuarially closer to death, it may seem that "natural death" would be the ideal, and that foregoing extensive medical intervention would be morally acceptable. It is not so clear, however; there is in fact neither any ethical nor legal basis for withholding CPR simply because of a person's age.

If CPR is not done, the person is dead within 4 - 15 minutes (except in unusual cases of hypothermia where longer survival is possible). The choice about whether to resuscitate, then, is an ultimately clear decision between death and a chance at continued life. The benefits are clear, and the risks must be seen in light of such dramatic benefits.

The risks are primarily two: 1) dying anyway, if CPR is ineffective, and that death being traumatic and lacking in dignity and 2) surviving with severe physical and neurological impairment, which to some people may be worse than death. If CPR is done and the person dies anyway, it will be a death accompanied by chest compression, a tube in the throat, needle sticks in the arteries and veins and possibly several electrical shocks. Of course, it is not known how the dying person perceives this, if at all. In the

very few studies asking survivors about their memories, none remember the CPR, although few of them would want it done again. To an observer, however, it is a procedure that appears to be full of chaos and brutality, and in this regard cannot help but have an effect on bystanders and family members in their attitudes about the death. It is an extreme departure from the serene image of "slipping away." Thus for someone who will certainly die anyway, or even for someone in whom physical and chances of success are extremely small, the "aesthetic" issue can be a part of the decision.

To survive with severe impairment is a fearful spectre for many people. The dreadful fate is being kept alive by machines in permanent coma (a "vegetable") or if awake to have sustained such serious brain damage that one cannot recognize even family members and is totally dependent for all aspects of care. Outcomes such as these are indeed possible, and in those series reported in the literature "poor outcomes" occur with variable frequency. The chance of brain damage increases with the length of time before CPR is initiated (i.e. minutes) and is also more likely if it is not done correctly. For this reason the decision to do CPR must be a wholehearted one if it is to be done at all. Since the event is sudden, the decision must have been made prior to the event.

These facts have many implications for institutional policies in acute care hospitals and in long term care facilities: 1) a decision must be made about the purchase and maintenance of equipment; 2) a decision must be made about the training of staff and 3) a decision must be made about who should be resuscitated, about how to decide and, most specifically for ethics and law, about the role of the elderly person himself or herself in this decision.

The decision not to resuscitate differs from other decisions to forego life-sustaining therapy because of the suddenness of the event and the need for a prior decision. With most other life-sustaining treatments, decisions can be made over hours, days or even weeks rather than in minutes. This gives the patient and the caregivers time for discussion and consideration of options. In most cases, if the patient is involved

in the decision about CPR it must be based on a verbal description of the procedure and its chances for success. (Even in survivors of previous CPR, they may not remember the event).

Many health professionals have difficulty in presenting such a choice to a patient and may underestimate the negative aspects (i.e. "If your health stops, do you want us to start it again?") or describe it in such a technical fashion that it is difficult for the patient to relate to the decision as personally relevant.

Because of all the clinical uncertainties, ethical complexities and information gaps we agree with many observers that health care institutions should have explicit policies about resuscitation. This is currently being discussed and implemented in many hospitals across the country, although relatively few have had any substantial experience yet. Policies consist usually of the following common components: 1) A statement that an order not to resuscitate can sometimes be justified, 2) a provision for review in the case of disagreement between principals, and 4) a plan for implementation. The development of policies is forcing hospitals and nursing homes to take a closer look at this issue. Federal policies should allow these decisions to occur at the local level and should not tie reimbursement to decisions about resuscitation.

Cardiopulmonary Resuscitation in the Elderly

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Cardiopulmonary Resuscitation: A Brief History

Death occurs within minutes if either breathing or heartbeat stop. Attempts at resuscitation of persons with cardiac or respiratory arrest are as early as recorded history, but modern techniques based on scientific understanding of human physiology, began as early as the sixteenth century when Vesalius inserted a reed into the trachea (windpipe) of a dog to perform artificial respiration. John Hunter, in nineteenth century Britain, was successful at resuscitating sailors drowned from boats on the Thames. The role of chest compression to mimic heartbeat and sustain bloodflow emerged more sporadically through history, and was not applied systematically to in-hospital cardiac arrest until 1960.

After this point cardiopulmonary resuscitation, attempts to restart heartbeat and respiration in persons momentarily dead, quickly became standard practice in American hospitals. The growth of resuscitation methods and technology was rapid at this point and offered a miraculous return from the dead for many patients.

This report will therefore review the techniques and technology of cardiopulmonary resuscitation, the current state of knowledge about utilization, outcomes and costs of this procedure, the ethical and legal aspects of decisions not to resuscitate and data on how those decisions are made including policies and guidelines in hospitals and long-term care facilities.

The Techniques and Technologies of Cardiopulmonary Resuscitation

Definitions

A cardiac arrest is the sudden unexpected cessation of pulse and blood pressure.

A cardiac arrest is synonymous with the absence of effective cardiac rhythm, contrac-

tions and blood flow and will produce loss of consciousness within seconds and death within minutes. Patients may have complete absence of any electrical activity of the heart (asystole) or electrical activity may be present. This activity may be an abnormally slow heart rhythm (bradycardia) or an abnormally rapid rhythm (tachycardia). Two common rapid patterns seen in cardiac arrest are ventricular tachycardia (VT), a rapid rhythm originating in an abnormal site and often seen in patients with coronary artery disease as a complication of a heart attack (myocardial infarction or MI) and a more dangerous pattern, ventricular fibrillation (VF) which is a chaotic, extremely rapid and irregular electrical activity. Ventricular fibrillation is ineffective in maintaining pulse, blood pressure, or circulation of blood. Some ventricular tachycardias may on occasion produce a pulse and blood which is a chaotic, extremely rapid and irregular electrical activity. Ventricular fibrillation is ineffective in maintaining pulse, blood pressure, or circulation of blood. Some ventricular tachycardias may on occasion produce a pulse and blood pressure and allow some blood flow. A major danger of VT is the tendency for it to rapidly deteriorate to VF. Because a cardiac arrest results in cessation of blood flow to the brain and muscles it is also accompanied by the cessation of breathing.

A respiratory arrest is the sudden unexpected cessation of effective breathing. It is most commonly due to obstruction of the airway, or respiratory muscle fatigue associated with lung disease. Respiratory arrest will be followed within minutes by gradual loss of consciousness and then by cardiac arrest due to the inability of the blood to supply adequate oxygen to vital organs (heart and brain) and eliminate carbon dioxide from body tissues.

In practice, in patients who have experienced a cardiac arrest it is often impossible to ascertain whether it was caused by a respiratory arrest. Since virtually all cardiac arrests are accompanied within minutes by cessation of breathing the term cardiopulmonary arrest is often used synonymously for cardiac arrest.

Cardiopulmonary resuscitation (CPR) is the collection of techniques and technologies to provide an airway, effective breathing and effective circulation to a person who has experienced a cardiac arrest. CPR consists of basic life support (BLS) which can be provided by trained laymen and medical personnel, and advanced life support, (ALS), provided by medical personnel, and consisting of more advanced techniques, and requiring additional technology, for airway management, electrical defibrillation, pharmacologic treatment, pacemaker insertion, etc. Community resuscitation refers to CPR initiated in a person who experiences cardiac arrest outside of the hospital. Community resuscitation is often begun by bystanders and continued by paramedical personnel while the patient is transported to a hospital or medical center emergency room where nurses, physicians and surgeons may continue the resuscitation. Patients who are successfully resuscitated are admitted to hospital intensive care or coronary care units. Hospital resuscitation refers to CPR initiated within the hospital, almost always in a patient who has previously been admitted to the hospital. Resuscitation is usually begun by nurses and continued within minutes by physicians and surgeons. The delay in initiating CPR following hospital cardiac arrest is shorter than community CPR and trained personnel and equipment needed for resuscitation are usually rapidly available.

Introduction

Death follows within minutes if either heartbeat or breathing stops. The heart pumps vital oxygen (and other nutrients and metabolites) to the brain which is the center of consciousness and of life. If breathing stops first, the lack of oxygen will itself cause fatal damage to the heart within very short period. If cessation of effective heartbeat occurs first, the brain is irreversibly damaged within minutes, spontaneous breathing cannot be restarted and the patient is dead.

The bellows function of the lungs was first understood even in Biblical times, and the components of the attempt to restore breathing were simple: airway and respiration. Airway refers to making sure that the upper airway is patent and not obstructed by the tongue or some foreign object. Then one breathes directly with the victims mouth while covering the nose to ensure that the air does not go into the lungs and not just out the nose. This technique is ancient and well understood.

The mechanisms of primary cardiac arrest rather than respiratory arrest were not well understood until the middle of this century, when pharmacological and electrical intervention became available. The two primary heart rhythm disturbances are asystole (absence of any electrical impulse), ventricular fibrillation (disorganized and ineffective electrical impulse) and electromechanical dissociation (normal appearing electrical impulse which does not cause contraction of the heart). The third (EMD) is much less common than the other two.

In the 1940's it was discovered that adrenalin (epinephrine) and procaine could sometimes restore heartbeat in asystole. Lidocaine was found to stabilize an irritable heart and to prevent recurrence of ventricular fibrillation if it could be once converted back to regular heart rhythm (normal sinus rhythm). Shortly thereafter, external electric shock was discovered to convert ventricular fibrillation to normal sinus rhythm. The shock would not work in asystole (cardiac standstill) because there had to be an electrical impulse of some sort to begin with, and then the shock would convert it to a more effective impulse. If there was no electrical impulse at all, the shock would not start one. Thus, the basic procedures of cardiac resuscitation include monitoring the electrocardiogram to see what kind of impulse, if any, is there, giving epinephrine to stimulate electrical activity in the heart (and to increase tension in the blood vessels), and giving electrical shocks if any impulse from the heart can be detected.

While the heartbeat is gone or severely compromised the lack of oxygen for body metabolism causes a buildup of acid in the blood (acidosis), which of itself causes the

system to be resistant to all these other measures. Thus the acid must be counteracted by giving bicarbonate into the bloodstream and by forcing oxygen into the lungs.

In 1960, research demonstrated that the ancient methods of chest wall compression could be effective in maintaining circulation in a patient who had no heartbeat. Until this time, cardiac arrest had been treated (if at all) by surgically opening the chest and directly massaging the chest. Successful application of closed chest massage along with increased technological capability to monitor heart rhythm and to safely apply electrical shock all contributed to the rapid and widespread acceptance of cardiopulmonary resuscitation in hospitals in the 1960's and shortly thereafter by emergency rescue teams. The basis of CPR, known as basic life support (BLS) (see Section II), were taught to community laypersons, high school students and others in an attempt to bring the ability to resuscitate out-of-the-hospital and into the community. There was a certain logic to this, because the success of CPR depended largely on how quickly it was instituted. If a person collapsed on the street, by the time an ambulance arrived it may have been too late. Successful data on community training in CPR comes from Seattle (see Section II) but their success has not been replicated in other communities. Some experts are now questioning the cost-effectiveness of large scale educational programs in CPR.

Advanced life support (ALS) includes the machinery which sustains life after the immediate, manual steps are taken. The most common such machine is the mechanical ventilator, which pumps oxygen into the lungs through a tube placed into the nose or mouth which extends into the trachea ("endotracheal tube"). An electrocardiogram is connected to monitor the function of the heart. Intravenous catheters are placed, often in the central veins of the neck or under the collar bone. Through these lines medications, bicarbonate and fluids are given. A pacemaker may be inserted through the veins also, but pacemaker insertion is not a common part of the resuscitation procedure. Neither cardiac standstill (asystole) or ventricular fibrillation can be reversed through

the use of a pacemaker. If the cause of the cardiac arrest is something which can cause other rhythm disturbances, for example a heart attack, then it may be necessary to insert a pacemaker once a heartbeat has been established.

There is very little about cardiopulmonary resuscitation that is specific to old age. Cardiac arrest is more likely to occur in an older person, since it occurs in every death, and death is more likely to occur in an old person. Critical and life threatening illness may also be more likely in an elderly person, and is the setting for many instances of in-hospital resuscitation. It is controversial whether age itself is associated with a diminished chance of successful resuscitation (see Ch. II), but it is clear that multi-system disease at any age diminishes chances of success. Logistical factors seem much more directly associated with success or failure of resuscitation than does age. In particular, a monitored or witnessed arrest is much more likely to be successfully resuscitated. A full discussion of factors involved in outcome of resuscitation is in Section II of this report.

Airway and Breathing

The first priority in resuscitation is the establishment of a patent airway to ensure that oxygen will be delivered once rescue breathing and circulation are begun. The most common airway obstruction is the base of the tongue lying in the back of the throat. The head-tilt maneuver with neck-life or chin-lift and the jaw thrust all move the tongue away from the trachea (see Fig. 1). Arthritis of the vertebrae in the neck, which is common in old age, may cause difficulty with this maneuver. Permanent residual damage such as spinal cord compression is rare in survivors. An airway obstructed with food or foreign material may be opened with four back blows followed by four manual thrusts (Heimlich maneuvers), repeated if necessary. This sequence is recommended by the National Research Council Conference on Emergency Airway Management¹, but controversy exists over whether back blows should be given first or at all, or only abdominal

thrusts. If the patient loses consciousness, the rescuer may be able to clear the airway with a finger sweep deep in the throat. Once the airway is open, breathlessness is assessed by looking for chest movement and listening and feeling over the mouth for air flow. If none is detected, rescue breathing is begun (see below).

Maintenance of the airway is aided by any of a number of devices (see Fig. 2), depending on the setting, condition of the patient, and skill of available personnel. A soft rubber nasopharyngeal airway inserted through the nose to the back of the throat keeps a path for air open behind the tongue in a conscious or semi-conscious person, and a rigid plastic or metal oropharyngeal airway inserted through the mouth does the same for the unresponsive patient. Both are easy to insert, may remain in place for a relatively long time, and may be used with ventilation. Paramedics sometimes use the Esophagel Obturator Airway (EOA) which consists of a blind tube with a cuff inserted into the esophagus. Air holes in the portion that is in the throat allow passage of air into the trachea, and a sealed mask around the external opening prevents leak from the mouth and nose. When the cuff at the end is inflated, air is prevented from entering the stomach, stomach contents are prevented from entering the trachea, and an open airway exists that can be used with a bag-valve device or mechanical respirator. The new Esophageal Gastric Tube Airway (EGTA) has an open distal tip connected to a port on the face mask through which a tube may be passed to decompress the stomach and further reduce the possibility of regurgitation and aspiration. Aspiration of stomach contents into the lungs is a common event during resuscitation and a cause of continued respiratory failure in survivors, as the inhaled material is damaging to the lungs and makes infection more likely.

The most effective method of securing the airway in an unconscious patient is endotracheal intubation. The endotracheal tube (ET) is a rigid plastic tube with an inflatable cuff inserted directly into the windpipe (trachea) and attached to a bag-valve device or mechanical respirator. A metal blade laryngoscope (to look into the vocal

cords) must be carefully used to visualize the trachea, and this procedure is done only by trained physicians and some paramedics.² Rheumatoid arthritis frequently affects the temporomandibular joint (where the jaw joins the skull) and could interfere with CPR by making the mouth difficult to open fully. Decayed or loose teeth may increase the difficulty of endotracheal intubation. Complications of tracheal intubation include esophageal intubation (putting the tube in the esophagus by mistake), trauma to the trachea or esophagus,³ and longer term damage to the vocal cords and narrowing of the trachea following tube remove.⁴

Rescue breathing without airway adjuncts is performed by one person mouth-to-mouth or mouth-to-pocket mask techniques. Mouth-to-mouth delivers about 18% oxygen (room air is 21%), and with a pocket mask oxygen can be increased by attachment to an oxygen source. A bag-valve unit ("ambu-bag") has a mask attached to a bag (see Fig. 3) and can deliver room air by placing the mask over the mouth and nose and squeezing the bag. Oxygen content can be increased by adding an oxygen source, and an oral or nasal airway is helpful. Higher concentrations of oxygen can be delivered with bag-valve devices, but higher volumes are generally delivered with mouth-to-mouth breathing. Stomach distention can result when an EOA or EGTA is not protecting the esophagus is not protected, or an tracheal tube is not being used directly. Bag-valve devices are therefore best used along with an ET or EOA as soon as is possible.

Mechanical respirators are not widely used during CPR (unless a patient is already on a ventilator), but CPR frequently leads to short or long-term mechanical ventilation. In both long-term and short-term survivors respiratory function is often inadequate immediately after a resuscitation, and recovery to independent breathing may take days or weeks.

Circulation

The rescuer must check for both respiration and for pulse, an indication of heart-beat, which can usually be felt best in the neck. Elderly people have stiffer arteries which may dampen the pulse somewhat, but should not obscure it completely.

Once the airway is secured and breathing begun, if a pulse is absent the rescuer should begin external chest compressions with the heel of the hand over the victim's sternum (breastbone) as shown in Fig. 4. The sternum is depressed 1.5-2 inches for second of compression time and one-half second of release. The recommended ratio of compressions to breath is 15:2 for one rescuer and 5:1 for two rescuers.

Several models of gas or oxygen powered mechanical devices to perform external chest compression with ventilation are available.⁵ They are used in cases where prolonged resuscitative effort may be necessary (hypothermia (low body temperature), drowning). Some are programmable, and all have the advantage of consistency in depth and length of compression, and need not be stopped for EKG or defibrillation. There appears to be no difference in overall complications between properly done standard external chest compression (SECPR) and properly used mechanical chest compression.⁶ They are not, however, a substitute for manual CPR by first responders. Mechanical chest compressors are found in some emergency rooms and intensive care units, but are not part of ambulance equipment (see Fig. 5).

To keep the brain alive, blood flow to the brain must be maintained at least 20% of normal.⁷ Animal studies recently measured blood flow to the brain during SECPR to between zero and 30% of normal.^{8,9} Lee, *et al*, found that the ability of SECPR to produce brain perfusion pressure adequate for 20% of normal flow is related to the "down time" between the moment of arrest and start of CPR.⁹ Methods to improve blood flow during SECPR are under investigation. "New CPR" is an experimental set of ideas that involves chest compression combined with lung inflation and abdominal binding^{10,11} to increase intrathoracic pressure. This increased pressure will be transmitted to the

carotid (neck) arteries to increase blood flow to the brain.⁸ However, "new CPR" may be more likely to produce liver and lung rupture. It is not basic life support (BLS) because it requires endotracheal intubation and specialized equipment. Interposed abdominal compression decreases flow to the lower body and enhances flow to the upper body.⁹ Thompson, *et al*, found no difference in outcome or frequency of vomiting between SECPR and IAC-CPR in a randomized, prospective study of 291 patients, 146 received SECPR and 145 IAC-CPR.¹⁰ Vomiting causes the possibility of inhaling or aspirating the vomitus, leading to serious lung damage. The MAST (Military Anti-Shock Trousers) suit is an inflatable garment that fits over the extremities and abdomen. When inflated blood volume and flow are enhanced in the trunk and the head. The MAST suit is probably useful in hemorrhage and trauma but may be harmful in patients with heart disease by increasing afterload (the pressure against which the heart must pump blood) (see Fig. 6).

After being discarded as a technique of resuscitation except in specific circumstances since 1960, open-chest cardiac massage (OCCPR) is once again gaining support.^{11,12} Studies show that OCCPR produce better cardiac output (blood flow) than SECPR¹³, and blood flow to the brain may be near normal.¹⁴ The JAMA Standards currently recommend OCCPR in penetrating chest injuries, cardiac tamponade (where the sack surrounding the heart fills with blood or fluid), or anatomical deformity that precludes closed chest compression. Proponents would add to this list failure to respond to SECPR.

Once the ABC's of basic life support have been initiated (airway, breathing, circulation) definitive care requires the institution of advanced life support by paramedics or medical personnel. These measures include establishing intravenous lines, administration of drugs to correct acidosis, suppress abnormal heart rhythms and support perfusion, electrical defibrillation to convert ventricular fibrillation to a normal rhythm. Most patients in cardiac arrest suffer a heart rhythm disturbance, most patients in cardiac arrest suffer a heart rhythm disturbance, most often ventricular fibrillation (62%), v tach

(7%), bradycardia (slow rate) and asystole (30%), and electromechanical dissociation (1%).¹⁹ Recent data associates earliest possible defibrillation with better outcome²⁰

The precordial thump (striking the sternum with the fleshy part of the fist) is a recommended initial maneuver in monitored in-hospital onset of v tach and v fib.^{21,22} The thump may itself convert the heart rhythm in these cases. Recent studies indicate, however, that it has no place in out-of-hospital resuscitation and may thump victims into a more malignant rhythm.²³

A defibrillator consists of an energy source (line or battery), charging circuit that builds electrical energy to a preset level stored in a capacitor, and a discharge circuit that delivers the stored energy to the patient (see Fig. 7). The energy is measured in joules and is delivered over 4 to 12 milliseconds through paddles properly placed across the chest (Fig. 8). The paddles also function to read the rhythm and display it on a monitor when left in place.

The amount of delivered energy depends on the amount of energy dissipated through internal resistance in the defibrillator^{24,25} and on the transthoracic resistance (TTR)²⁶. The TTR depends on paddle size, paddle composition, paddle-skin contact, and paddle pressure. Optimum paddle size is 13 cm in diameter. Larger or smaller paddles are associated with less success^{27,28} and smaller paddles with myocardial necrosis.²⁹ A copper alloy provides the lowest TTR of metals tested.³⁰ Paddle-skin contact is facilitated by the use of one of many available high and low resistance gels.³¹ The recommended paddle pressure is 25 lbs.

Controversy over the optimal amount of energy that should be delivered has raged since the early 1970's. In 1975 Tacker concluded that most defibrillators in use then had inadequate output (200 joules) to defibrillate many human adults.³² More expensive high-output (500 or more joules) defibrillators became available. In 1978 Pantridge reported that 200 joules was effective to defibrillate 95% of patients, and 100 joules in 60%.³³ Since then many reports of high-dose vs. low-dose defibrillation have appeared in

the literature, and the controversy has not been settled. The ACLS manual and the current JAMA Standards recommend an initial attempt of 200-300 joules, repeated if necessary.

Since early defibrillation has been shown to be one of the most important factors in favorable outcome of out-of-hospital cardiac arrest,^{34,35} many of the efforts in the last 20 years to improve CPR survival have been directed at shortening the time to defibrillation. The development of the portable defibrillator in the 1960's enabled mobile intensive care units to defibrillate patients at the scene, and in the 1970's paramedics were trained to recognize rhythms and use defibrillators. In the 1980's programs are being developed for less trained Emergency Medical Technicians (EMTs), spouses and family members, and lay people at workplaces to defibrillate patients with the use of automatic external defibrillators (AEDs). A semi-automatic external defibrillator has two adhesive electrodes attached to the patient's chest. The electrodes read the rhythm, decide whether v fib is present, and then advise whether a shock is needed. The operator must still decide whether or not to deliver the shock, and must push a button to complete the procedure. Fully automatic external defibrillators are also available. These also sense cardiac rhythm through chest electrodes, although some models have one electrode attached to an oral airway. All the operator must do is attach the device properly and press the "ON" switch. No decision-making is required, making it possible for less trained EMTs, family members, and others to deliver early defibrillation. The Heart-Aid is a model of AED currently being tested in Seattle. Fig. 9 shows the user guide supplied with the Heart Aid outlining the steps for use which are combined with BLS.

The development of these automatic defibrillators raises many questions recently explored by Cummins.³⁶ One of the major problems is deciding whether the patient is actually in cardiac arrest. Many conditions can mimic cardiac arrest to untrained personnel, including fainting, drug intoxication, seizures, shock, and even alcohol ingestion. Under these conditions and other situations potential errors in reading the rhythm may

arise from loose ends, background electrical noise, or unusual rhythms which may fool the fibrillation detector, and a potentially lethal shock may wrongly be delivered. Second verification systems to confirm cardiac arrest are being explored including breath detectors, chest movement detectors, gag reflex detection by the oral airway electrode, and others. This raises another problem in that time required for such second verification could negate the advantage gained by early access to the defibrillator. In the hands of trained paramedics a second verification system would be unnecessary.

Stopping CPR long enough to apply the defibrillator and let it decide what to do is another problem. Current JAMA standards recommend that basic CPR not be interrupted for more than 5 seconds. Available AEDs require CPR stop for at least 10-15 seconds. The effect on outcome of these longer stops is not known. Deterioration of the skill to properly use the AED by lay people, family members, and EMTs where cardiac arrest is not common (e.g. rural areas) is another problem, since it has been shown that BLS skills deteriorate rapidly without retraining.^{37,38}

A key difference between EMT manual defibrillation and EMT automatic defibrillation is that in manual programs that EMTs must learn to recognize v fib and treat it appropriately. The training, supervision, continuing education and recertification are more difficult, more expensive and time consuming than are programs with AEDs. Research is underway to find out if the automatic defibrillators when used by EMTs perform as well as manual defibrillators.

Automatic defibrillators are being developed experimentally which use the tongue as the site of one of the electrodes instead of the sternal area. It has been found that the impedance is higher, but defibrillation using this "vertical" pathway is effective.³⁸ Finally, for very high risk patients an implantable automatic defibrillator was developed in 1980 and has been used in several hundred patients with good results so far. However, the necessity of surgery, the high cost, and the small population of potential recipients limits its widespread use.

Public health issues are also raised. Currently these items are available only by prescription. Will this continue? Who pays for prescribed home use of AEDs? What control will be over these machines once they become widespread in the community?

Drugs

Oxygen: is one of the "truly essential drugs in resuscitation and emergency cardiac care" (ACLS p. 99), and should be used in the presence of hypoxemia of any cause. It may be provided by mask, nasal cannulae, bag-valve device or mechanical respirators at varying concentrations.

Sodium Bicarbonate: is used to treat the acidosis caused by accumulation of lactic acid from anaerobic metabolism and carbon dioxide retention. Acidosis is life threatening and may interfere with the patient's response to resuscitation.^{40,43} It is treated by effective ventilation to decrease retained carbon dioxide and intravenous administration of boluses of sodium bicarbonate as needed. Excessive sodium bicarbonate can lead to alkalosis, sodium and water overload, and paradoxical cerebral spinal fluid acidosis.

Epinephrine (adrenalin): Injected into the veins or sprayed into the trachea, epinephrine increases heart rate, heart contractility, blood pressure, and perfusion pressure to vital organs during chest compression. It has a direct stimulatory effect on the heart and constricts peripheral blood vessels. It also renders fine ventricular fibrillation more susceptible to electrical shock. The increased contractions raise the heart's demand for oxygen. Since increased perfusion pressure may be the most beneficial effect in CPR, drugs that constrict peripheral vessels without increasing the heart's demand for oxygen may be even more useful (methoxamine, phenylephrine).⁴⁴ Norepinephrine may dilate coronary arteries.

Dopamine: is useful in cardiogenic shock and hypotension; at low doses it dilates renal and mesenteric blood vessels, at moderate doses it increases cardiac output, and at high doses constricts blood vessels. Dobutamine increases cardiac output.

Atropine: blocks slowing of heart rate by the parasympathetic effect of the vagus nerve, and allows an increase in heart rate and contractility by the sympathetic nerves to predominate. It may be useful in severe slowing of the heart accompanied by shock or infrequent abnormal beats, heart block, and asystole. Complications of atropine include ventricular fibrillation and tachycardia, and increased oxygen demand by the heart with increased heart rate, which may cause heart damage from a decrease in blood supply.

Lidocaine, procainamide and bretylium: are used to treat and in certain cases prevent dysrhythmias. Recent reports support the effectiveness of all three in certain situations.^{45,46,47}

Verapamil: is a newer calcium channel blocker used to treat supraventricular dysrhythmias and also decreases contractility in ischemic hearts. It may be useful in preventing reperfusion injury after resuscitation and in electromechanical dissociation and other arrhythmias.⁴⁸

Calcium Chloride: has been recommended and used since the 1920's in resuscitation, and is currently recommended for use in EMD and other dysrhythmias by the JAMA Standards and the AHA. Recent studies do not support its effectiveness and suggest that it may even be harmful by increasing intracellular damage.^{48,49,50,51} Its role is being reevaluated.

The pharmacology and pharmacokinetics of the elderly are known to be different because they have less muscle mass, more fatty tissue, and have altered blood flow to the liver and kidneys (two main organs of drug elimination and metabolism). How these drugs used in resuscitation are affected by these differences is not known, and no guidelines for use in the elderly are given. Anecdotal evidence suggests that there may be increased variability in response, and this is an area in which research would be very helpful.

Cerebral or Brain Resuscitation:

Cerebral preservation refers to aspects of therapy initiated during the resuscitation that may minimize anoxic damage and reperfusion injury. Drugs that decrease brain metabolic rate (e.g., barbituates) have been tried for this reason. Cerebral resuscitation is therapy initiated after restoration of spontaneous circulation, intended to preserve brain function. Most experts today are skeptical of the success of these measures. Several drugs are under investigation in animal models, including barbituates, calcium antagonists, and iron chelators.^{53,54}

Pacemakers in CPR:

Pacemakers are of limited value in the majority of out-of-hospital arrests, but transcutaneous (external) pacemaking is safe and effective applied to conscious patients either briefly during sudden bradycardia (slow heart beat) or for a short test period to establish a pacing threshold in high-risk patients in whom prophylactic transvenous pacing would otherwise have been performed. But this procedure is not effective if there is no heartbeat.

Problems in CPR:

Deterioration of BLS and ALS skills occurs rapidly if not used frequently, but there is no evidence that this effects survival. There are few health professionals other than interns, residents, paramedics and emergency room personnel who use these skills often enough to maintain them. Lay persons, police and medical students who were all trained in BLS but did not use these skills were found to have a sharp decline in these skills after two years.⁵⁸ Even those who use these skills routinely have been found to

lose some skill but psycho motors skills (e.g., intubation) were maintained.⁵⁹ Cobb suggests that this skill deterioration might not effect survival.⁵⁸

Goldman looked at the frequency and duration of CPR to determine whether or not CPR was being performed according to AHA standards.⁶⁰ He found that the frequency of interruptions in one hospital was 0.41 per minute, 17% of which lasted longer than 20 seconds. Current AHA standards provide no interruption should last longer than 5 seconds, even for intubation. 80% of the longer interruptions were unjustified.⁶⁰ Although many factors contributed to outcome, survivors had fewer long interruptions. Though no age breakdown was given, the mean age of patients undergoing resuscitation in this study was 66.2, range of 46-82. No other data on performance of in-hospital resuscitation is available and this is another area in which research would be helpful.

The deterioration in skills raises questions of frequency of retraining, whether inadequate or poorly performed CPR is better than no CPR. Research is needed in how CPR is actually performed and deviations from the standards.

The frequency and duration of interruptions of CPR in hospital is 0.41 per minute, 17% of which were greater than 20 seconds in duration. (Standards says not interruption should be greater than 5 seconds, even for intubation). 80% of long interruptions were unjustified in the Goldman study. Clearly these factors affect outcome, and must contribute to the wide variability in outcome studies (See Section II).

What percent of house officers, nurses, lay people are trained in BLS and ALS? In hospitals, nursing homes, retirement centers, hospices.

I. Availability of Equipment

Since early defibrillation is the single most effective positive outcome factor in ventricular fib, are defibrillators readily available in hospitals and nursing homes? Most hospitals have the necessary equipment for BLS and ALS. If sustained intensive care is

not available, smaller hospitals will transfer unstable resuscitated patients by ambulance or helicopter to a larger facility. Nursing homes, however, are mostly not equipped for ALS and many do not even train their staffs in BLS. More nursing homes are realizing the need to have trained staff and some kinds of equipment, knowing that this will force the question of a DNR policy (see Section IV). Some draw the line at giving drugs but withholding defibrillation, even though defibrillation is probably more effective than drugs because the condition that it treats has a better prognosis. The image of a defibrillation in a nursing home has probably seemed too high-tech and aggressive. If a simple intervention, i.e., shock, is more likely to be successful, they may be more appropriate for nursing homes than other technical modalities. Again, more research is needed.

When to Stop CPR:

There are no clear widely accepted guidelines for termination of cardiopulmonary resuscitation (CPR). Brain death cannot be assessed before or during resuscitation because 6-24 hours of observation are needed, along with more than one flatline EEG. Other signs, such as lack of pupil response and reflexes, are unreliable indicators of brain death. This is particularly true in the elderly who may have unreactive pupils from cataract surgery, and are also often taking multiple medications that may affect neurologic responses.

The 1974 JAMA Standards provided that basic life support measures be continued by physicians until "The patient recovers or is pronounced dead."⁶¹ The 1980 standards provide CPR be continued until recovery or "The patient is found to be unresuscitable...and is pronounced dead". It does on to define "unresuscitable" as "Failure of properly applied BLS and ACLS to reestablish effective cardiovascular function,..."²¹ McIntyre agrees that "the decision to discontinue resuscitative efforts should be based on cardiovascular unresponsiveness"⁶² adding that cardiac death has then supervened. He also cautions against prolonged resuscitation because he believes the risk for

permanent brain damage increases with duration of resuscitation and "litigation is more likely to follow when the patient survives with permanent brain damage than when the patients dies."⁶² However complete recovery has been reported following as long as 2 to 3 hours of resuscitative effort, usually associated with hypothermia in drowning⁶³ or with drugs overdose.

Specific guidelines were proposed by Eliastam in 1979 for when resuscitation should be discontinued or not attempted:

Causes of apnea and pulselessness known to have exceeded 10 minutes, no response after more than 30 minutes of advanced cardiac life support (ACLS), no ventricular EKG activity after more than 10 minutes of ACLS, and preexisting terminal illness.⁶⁴

These guidelines are not widely used, and examples of complete recovery can be found for patients whose resuscitation would have been terminated under the first three criteria.^{65,66,67}

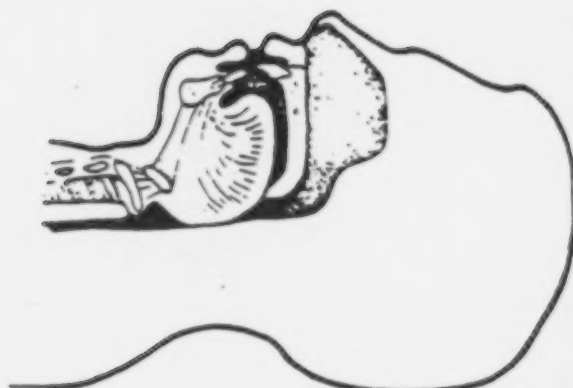
Chipman recommends that "no criteria be followed for ceasing CPR"⁶⁸ because he found that doctors were not consistent in determining when to stop CPR, and that years in practice tended to make doctors less aggressive about resuscitation. He also found that a non-urban background decreased aggressive measures and those with surgical training tended to cease CPR sooner in those over 75. This substantial variability suggests to him that no criteria could be appropriate, and the decision to stop CPR must be made on a case by case basis.

Although some advocate no resuscitation for those over 65,^{69,70} age is not a criterion itself in most United States studies.^{71,72,73} Nursing home status was associated with the decision of 18% of doctors to resuscitation in the Chipman survey.⁶⁸ That study, like many others (see Section III) is based on questions about a hypothetical case.

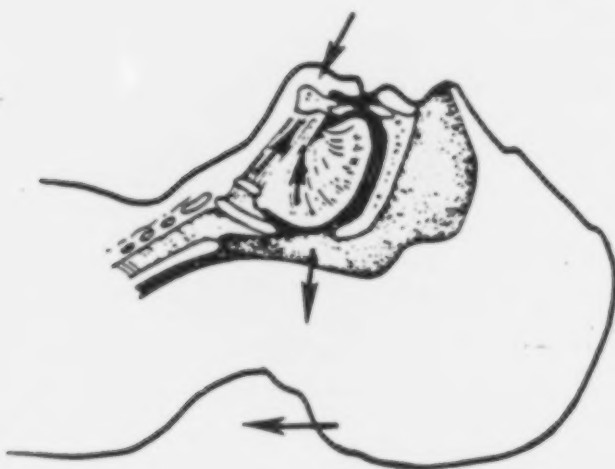
Research is needed to determine actual practice for stopping CPR in various situations, and whether age, nursing home residence, dementia, patient and family preference and other factors enter into the decision. This data is an important basis for the development of sound ethical politics.



The rescuer should look, listen, and feel for signs of spontaneous respiration. Note that rescuer is simultaneously opening airway by head tilt method.



Base of relaxed tongue rests against posterior pharynx, causing airway obstruction.



Head tilt lifts tongue from posterior pharynx, opening airway.



Head tilt method of opening airway. Note position of hands.



Modified chin lift. This method has limited use, since obtaining a seal for mouth-to-mouth ventilation is difficult.



Jaw thrust method for opening airway.

Fig. 4

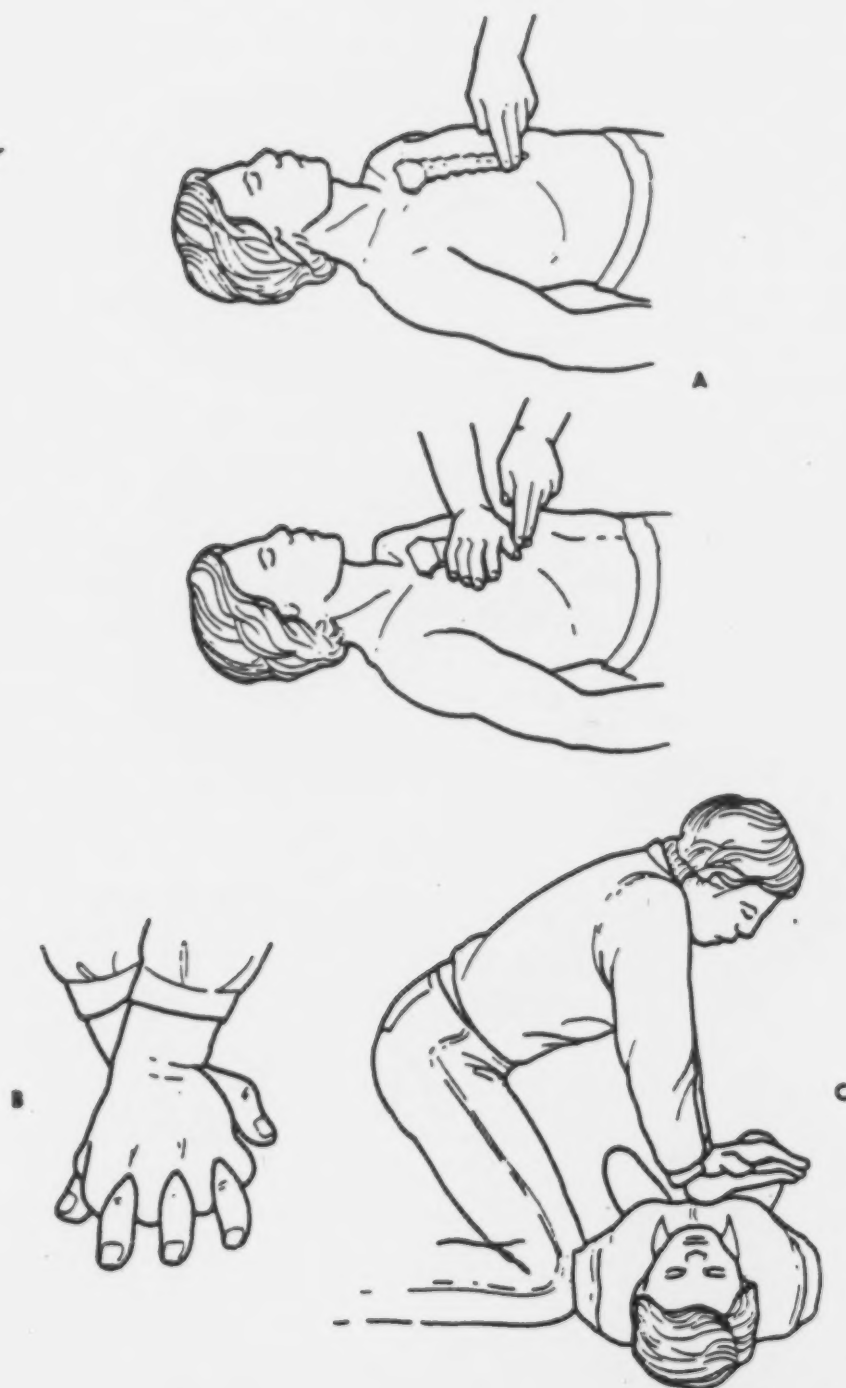
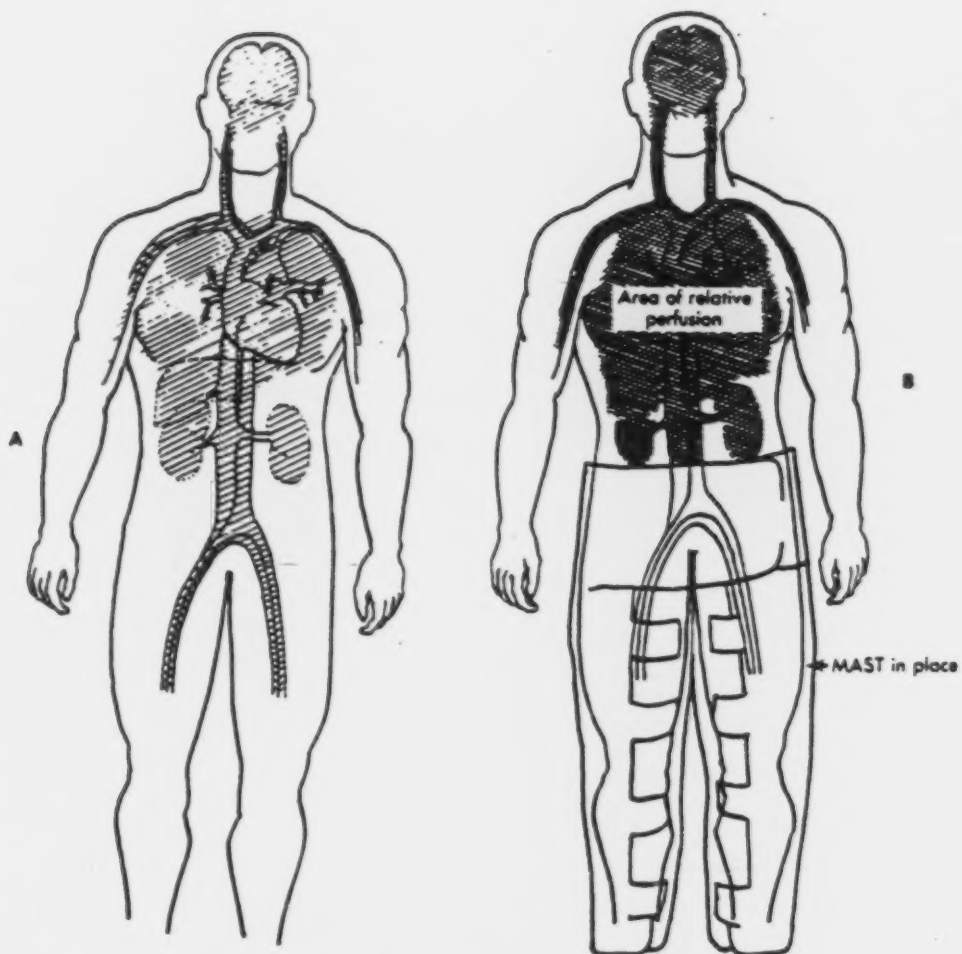


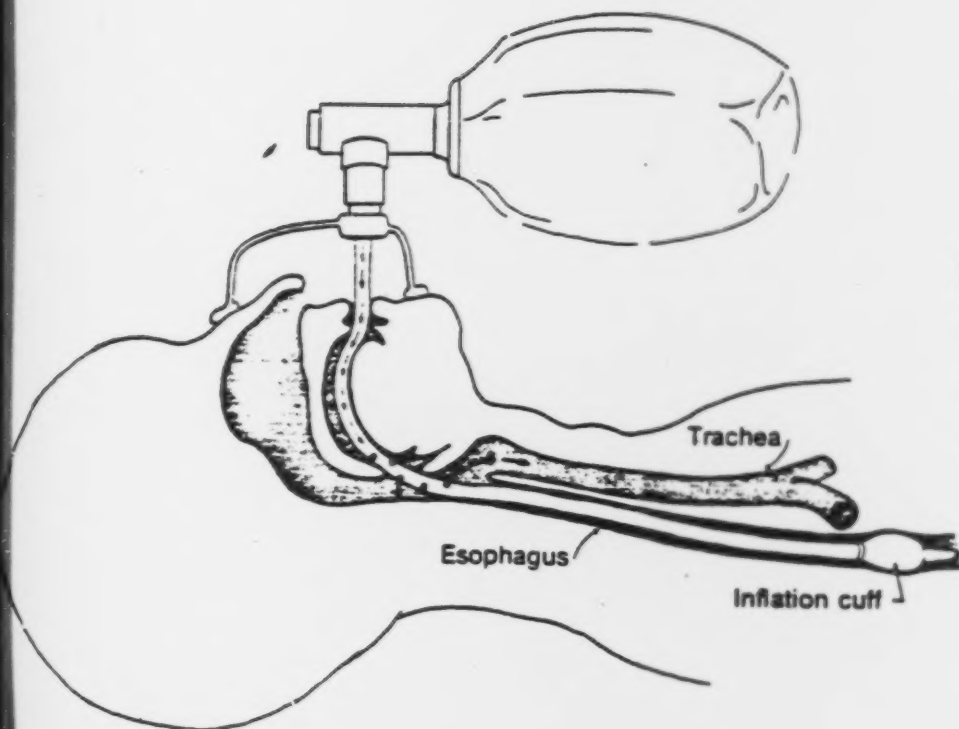
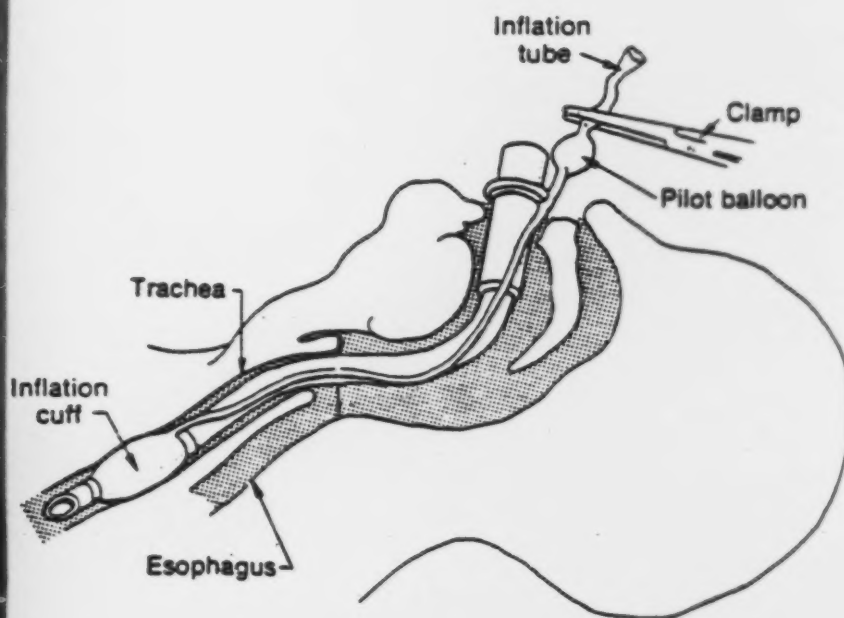
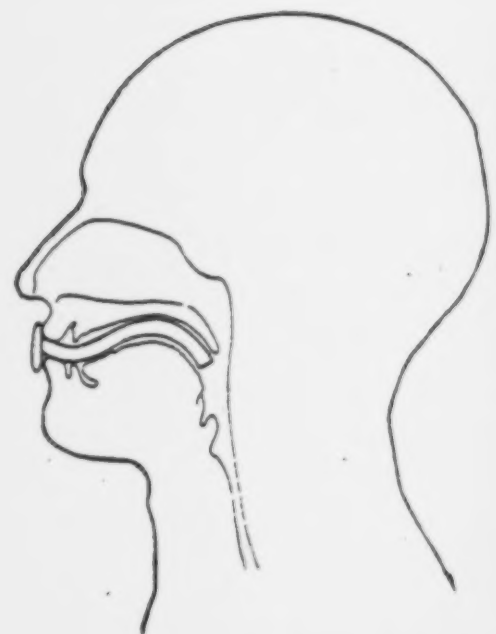
Fig. 4 A, Determination of correct hand placement by measurement from xiphoid. B, Technique of interlocking fingers. C, Correct position of rescuer. Note rescuer's shoulder directly over patient's sternum.

FIG. 6



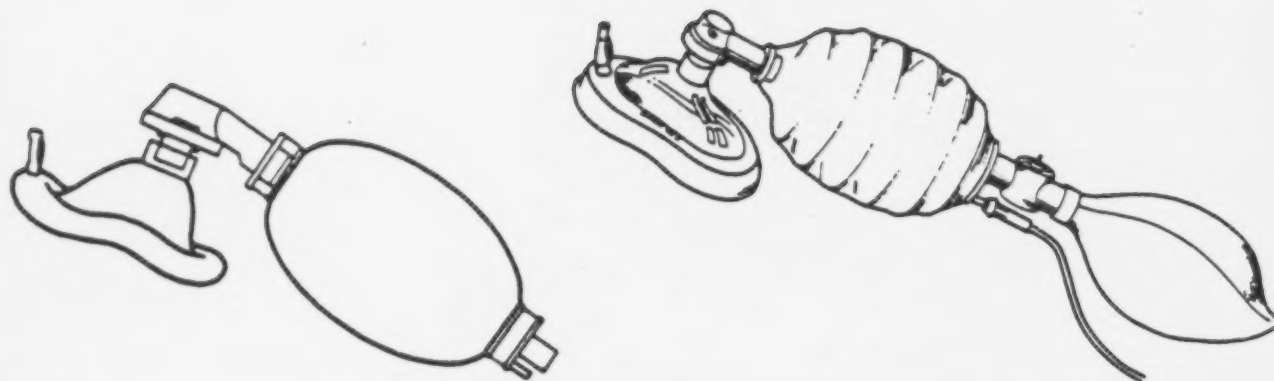
A, Circulation before MAST inflation. B, Autotransfusion of blood to essential organs after MAST inflation.

FIG. 2 AIRWAYS

Esophageal Obturator Airway (EOA)
in placeNasopharyngeal Airway
in placeEndotracheal Tube (ET)
in placeOropharyngeal Airway
in place

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Fig. 3



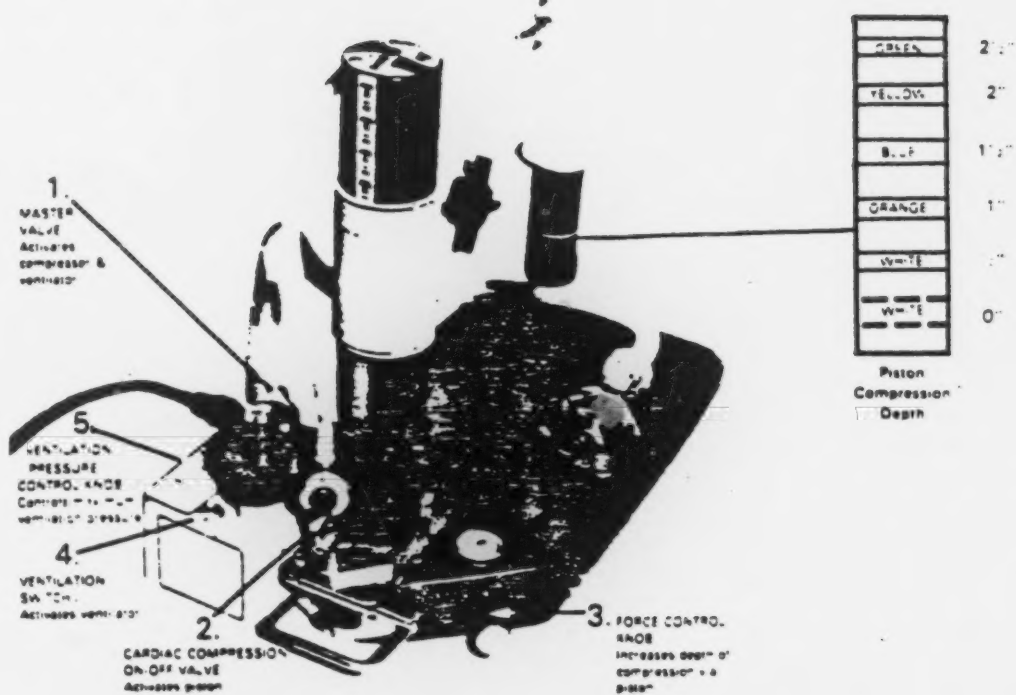
Typical Bag-Valve-mask Devices



Pocket Mask in place

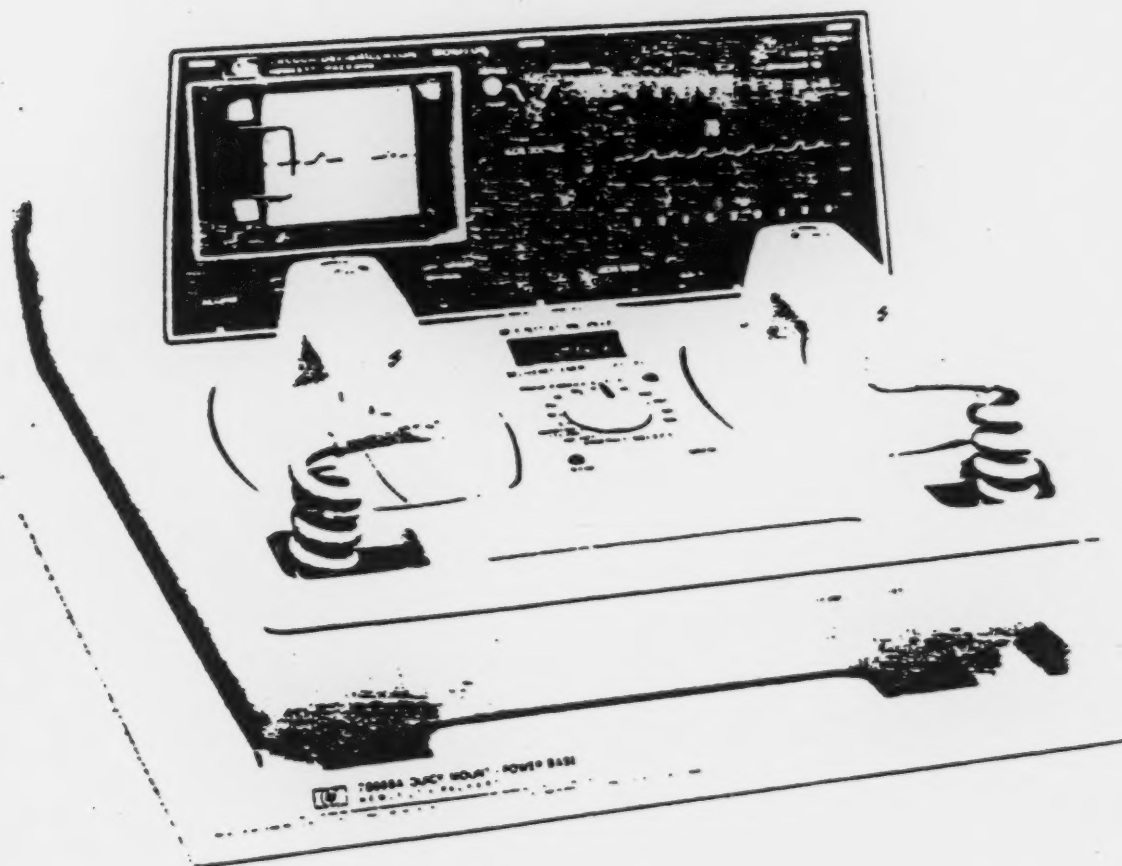
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FIG. 5



Example of oxygen-powered chest compressor. (Courtesy Dixie U.S.A., Inc., Houston, Texas.)

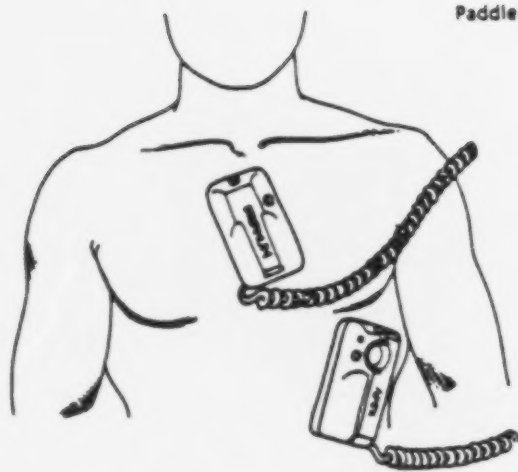
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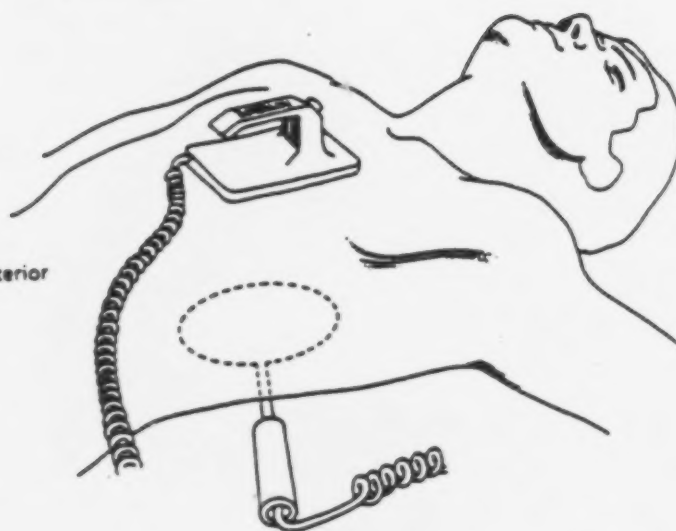
Modern DC defibrillator. (Courtesy Hewlett Packard Co.)

Fig. 8

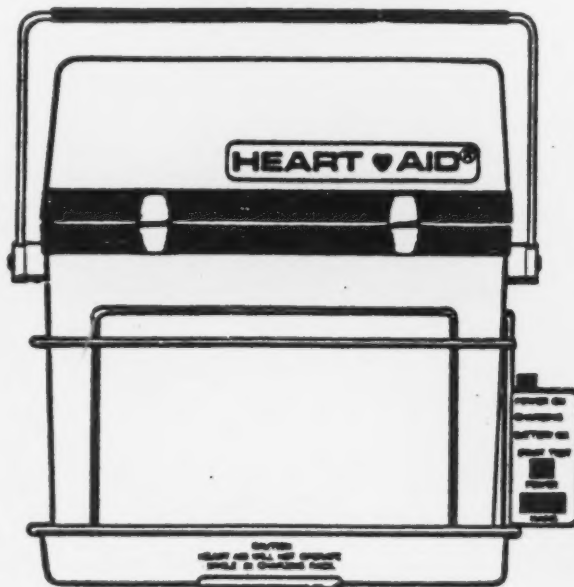
Paddle placement for defibrillation.



Anterior-posterior
paddle placement.



HEART AID GUIDE



HEART ♥ AID® GUIDE

1

**ASSESS ABC's****AIRWAY OPEN****BREATHING ?**

LOOK, LISTEN & FEEL

**CHECK PULSE**

2

**CALL EMS**

- ADDRESS
- CPR IN PROGRESS
- BRING H.A. TO PATIENT

3

**CPR ONE CYCLE**

2 BREATHS 15 COMPRESSIONS

4

**CONNECT
HEART AID**

5

HEART AID

**TURN ON**STAND BACK
WHEN VOICE STOPS
COUNT TO 15

COUNT TO 15

6

HEART AID

**TURN OFF**

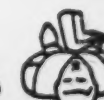
7

**CHECK PULSE**

IF PULSE MONITOR
BREATHING
IF NO PULSE

CPR ONE CYCLE

8



REPEAT 5-8
UP TO 3X THEN
CONTINUE CPR
UNTIL HELP
TAKES OVER.

2 BREATHS 15 COMPRESSIONS

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Definitions

A successful resuscitation is defined in this report as the presence of a pulse and blood pressure in the patient at the end of a resuscitation attempt. An unsuccessful resuscitation, by definition, has a fatal outcome, and at the end the patient will be pronounced dead, usually by the physician who directed the resuscitation attempt. At the end of a successful community resuscitation the patient will be admitted to a hospital, and therefore the hospital admission rate of patients receiving community resuscitation is a practical epidemiologic measure of the success rate of community resuscitation. A resuscitation may last a few minutes to many hours, but most commonly lasts 30-60 minutes. At the end of a successful resuscitation a patient will have a pulse and detectable blood pressure. The heart rhythm may be abnormal or require continuous intravenous medication or a pacemaker and the patient may require continuous infusion of medicine to support the blood pressure and maintain effective blood flow. The patient's brain may have sustained potentially irreversible anoxic injury during the cardiac arrest and resuscitation. Patients successfully resuscitated are critically ill, due to the presence of serious underlying diseases, complications of the cardiac arrest, and the risk of a recurrent cardiac arrest.

The survival rate of CPR is defined in this report as the proportion of all patients originally experiencing the cardiac arrest who are discharged alive from the hospital. Since virtually all patients resuscitated from a cardiac arrest are admitted to a hospital, this definition applies to both community and hospital CPR. The duration of hospitalization for patients successfully resuscitated is quite variable, and there is a high death rate during their hospital stay. The survival rate is the most relevant measure to use to assess the outcome of CPR. The hospital discharge rate of those successfully resusci-

tated does not include persons who experience a fatal community cardiac arrest, and would overestimate the actual outcome of community resuscitation. Patients must have reached a minimal level of stability in their clinical states to be discharged from a hospital. The survival rate does not specify the functional status of patients or distinguish between patients who are discharged to their home, to a rehabilitation hospital or to a long-term care facility.

The mortality reduction rate provides a useful estimate of the reduction in the hospital mortality rate that results from hospital cardiopulmonary resuscitation.

$$\text{Mortality reduction (\%)} = \frac{\text{Hospital CPR Survivors Home}}{\text{Hospital CPR Survivors Home} + \text{Hospital Deaths}} \times 100\%$$

If there were no hospital cardiopulmonary resuscitation policy or practice the hospital CPR survival rate would be zero, and the mortality reduction would be zero. As patients are successfully resuscitated and survive to hospital discharge, the hospital mortality is reduced because some patients who would have died in-hospital now survive and are discharged alive. Therefore as the hospital CPR survival rate increases hospital mortality is reduced. The mortality reduction rate provides an estimate of the contribution of CPR to the reduction in hospital mortality. Estimates suggest that the current mortality reduction due to CPR is approximately 6%.

Nature and Source of Available Data

Information on the utilization and outcome of cardiopulmonary resuscitation (CPR) in the elderly can be obtained from the general medical literature on cardiopulmonary resuscitation. Many, but not all, papers report the mean age, age range, or the proportion of patients receiving CPR who are above the age of sixty five. Few reports

include detailed age specific rates of the utilization and outcome of CPR. In the following section age specific utilization rates and outcomes are reported in detail whenever available. Although additional data on CPR for elderly patients may be located in hospital records, emergency room logs, ICU data bases, or reports of paramedic or ambulance calls, this data is not readily available and has not been included in this section.

The sudden and unexpected nature of a cardiopulmonary arrest that prompts an attempt at cardiopulmonary resuscitation limits the quantity and quality of information available. Information on the health and medical condition of elderly patients experiencing a cardiac arrest is often unavailable at the time of arrest. In many cases, underlying medical diseases such as coronary artery disease were asymptomatic or undiagnosed at the time of the cardiopulmonary arrest. In unsuccessful resuscitations there is no further opportunity for medical evaluation and the circumstances of a sudden unexpected death often preclude the systematic accumulation of data from the patient's family, friends, or physician. An autopsy is not performed on many patients who die following a cardiopulmonary arrest, and the sudden death is attributed to coronary artery disease. An autopsy may fail to indicate the cause of death in some patients with rapid fatal collapse.

The medical literature informs physicians of new information, important advances, unusual or surprising results, unrecognized or rare complications, and critical reviews or reappraisals of medical problems. Many papers report findings that therefore may not be representative of current practice or applicable to other circumstances. Medical literature written by physicians at medical schools and university teaching hospitals reporting results of CPR may not apply to utilization and outcome at community hospitals, hospitals not affiliated with medical schools, or hospitals without a house-staff. The peer reviewed medical literature is not designed to provide data for quality control or to monitor outcomes that may be regularly needed for public health purposes.

A careful and critical scrutiny of the medical literature on cardiopulmonary resuscitation reveals several methodologic problems in the evaluation of the utilization and outcome of CPR in the elderly. In many reports the definitions of cardiopulmonary arrest differ, patients undergoing CPR are inadequately described, followup information is incomplete, and the population at risk of CPR or from which patients were obtained is not described or adequately reported. In this report the best data on CPR in elderly is presented, deficiencies are identified, and recommendations concerning reporting are noted.

It is important to carefully describe patients experiencing CPR and the setting in which CPR occurs since the outcomes can vary widely in different patient populations and different community or hospital settings. This section focuses on community and hospital CPR, and whenever possible indicates any special circumstances or unusual conditions of patients.

Community resuscitation refers to a cardiopulmonary resuscitation occurring in the community, often initiated by bystanders and continued by paramedical personnel or emergency room nurses, physicians or surgeons. Hospital resuscitation refers to cardiopulmonary resuscitation occurring in a hospitalized patient, usually initiated by nurses rapidly assisted by physicians and surgeons. The different circumstances surrounding the occurrence of the cardiac arrest, the delay in initiating resuscitation, the availability of training, the experience of persons performing resuscitation, and the availability of additional resources for resuscitation result in different successful resuscitation rates and survival rates, and therefore community resuscitation should be distinguished from hospital resuscitation.

Many reports of CPR include patients with trauma, traumatic injury (e.g., automobile accident), a group of patients in which the indications for CPR resources needed and outcomes may differ from those of groups without trauma. Similarly, reports of the indication and results of CPR in patients with hypothermia or cold water drowning may

not apply to other patients. This project does not include papers reporting the resuscitation of patients who are victims of trauma or drowning because these patients are not representative of most patients experiencing a cardiac arrest and their resuscitation requires different resources and is associated with different outcomes. Further careful evaluation is required to distinguish whether reports of CPR include all respiratory arrests, only cardiac arrests, ventricular tachycardia or ventricular fibrillation arrests (VT/VF arrests), cardiac arrests in the setting of acute myocardial infarction, or cardiac arrests in patients without myocardial infarction (survivors of "sudden death"). Utilization and outcome in these groups differ, and the elderly patients experiencing CPR may not be uniformly distributed in these groups.

Occurrence of CPR

Cardiopulmonary resuscitation in response to a cardiopulmonary arrest occurs in two very different settings: community or out-of-hospital CPR and hospital CPR. It is important to note there is no data on the incidence of CPR in special locations where elderly may reside such as nursing homes, hospices, residence homes, or long-term care facilities.

Representative medical literature from several centers reporting community CPR have been collected in Table 1. Reporting institutions vary from single medical centers to paramedic programs from a geographic area that include several hospitals. Papers typically report approximately 150 cardiopulmonary resuscitations per year, although some reports contain substantially fewer arrests. The mean age of patients resuscitated is 62 years. The male/female ratio is 3.1, or equivalently 76 percent of resuscitations occur in men. Detailed age distributions of elderly patients receiving CPR in the community are rarely reported in medical literature. Overall 50 percent of community cardiac arrests occur in persons who are 65 years of age or older. 30 percent occur in persons 60 - 69 years of age, 20 percent in persons 70 - 79 years of age, 15 percent in

persons 80 - 89 years of age, and less than 1 percent in persons 90 years or older. The age distribution of patients receiving community CPR is shown in Figures 1 and 2. ^{4,9}

Table 1 - Occurrence Community Resuscitation

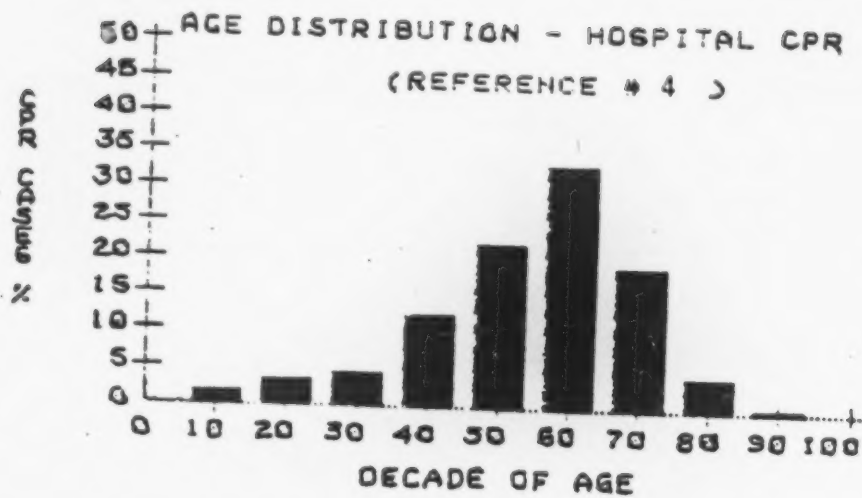
Study	Year	Region	Referral Hospital	CPR*/Time	Mean Age (Range)	Sex (M/F)
Baum (3)	1974	Seattle	Area hosps.	146/3 yrs	60.4	124/2
Cobb (8)	1975	Seattle	Area hosps.	234/51 mos	59.8 (17-90)	183/5
Eisenberg (11)	1979	King Co., WA	Area hosps.	604/17 mos		
Eisenberg (13)	1979	King Co., WA	Area hosps.	283/1 yr		
Rockswold (30)	1979	Hennepin Co., Minnesota	Co. med ctr	514/2 yrs	63 (15-86)	
Eisenberg (14)	1982	King Co., WA	Area hosps.	1567/61 mos	63 (men) 70 (women)	1202/
Guzy (19)	1983	Los Angeles	Area hosps.	300/1 yr	65±16**	204/9
Longstreth (24)	1983	Seattle	University Med Center	459/10 yrs	62 (17-98)	353/1
Tresch (41)	1984	Milwaukee	Co. Hosp.	139/9 yrs	60±12.7** (15-91)	111/38
Gudjonsson (17)	1978	Iceland	City Hosp.	222/3 yrs	64.8 (2 mo.-88 yr)	166/56
Agnew (2)	1983	New Zealand	Area hosps.	405/1 yr	-	-
				65 survivors	60.4 (34-84)	44/21

*CPR=Cardiopulmonary Resuscitation

**Standard Deviation

000047

Figure 1.



Source: Bedell (4)

Strikingly absent from many reports are the number of people in the referral area covered by hospitals or paramedic services, the number of ambulance calls, and number of emergency room visits. It is therefore difficult to provide a precise estimate of the incidence of CPR. The best available data ^{7,12} suggests that cardiac arrest occurs in approximately 58 to 71 per 100,000 persons per year, of which 51 per 100,000 are due to cardiac disease. The total number of community cardiac arrests each year in the United States in the elderly is approximately 69,000 to 85,000. This estimate is calculated from the estimate of the yearly incidence of cardiac arrests of 58 - 71 per 100,000, the age distribution of cardiac arrests (50 percent of cardiac arrests in persons 65 years or older), and the U.S. population of approximately 238 million.

Table 2 - Occurrence of Hospital Resuscitation

Study	Year	Hospital	CPR*/Time	Age (Range)	Sex M/F
Turk (42)	1954		42/5 yrs	(3 mo.-88 yr)	
Coskey (8)	1978		1155/10 yrs.	>65: 54%	
DeBard (9)	1981	Teaching hosp Dayton, Ohio	1073/6 yrs	60	
Bedell (4)	1983	Beth Israel; Boston	294/18 mos.	< 60: 20% 60-70: 23% 70-80: 34% 80-90: 19% 90+: 4%	160/34
Szczygiel (37)	1981	Kansas Univ. Medical Center	346/2 yrs	62	66/26
Aderka (1)	1984		43	(61-81)	
Scaff (32)	1984	Community; Corpus Christi, Texas	300/2 yrs.	>70: 43%	176/124
Hill (20)	1977	2 teaching hosps; Nottingham, England	182/32 mo.	≤ 64: 60% ≥ 65+: 40%	1521/126
Scott (33)	1981	Edinburg Royal Infirmary	78/6 mos.	< 60: 27% 60-69: 37% 70-79: 32% 80-89: 3%	
Dohi (10)	1983	2 hospitals; Sapporo, Japan	78/6 yrs	(2-79)	
Sowden (34)	1984	2 hospitals Bristol, England	108/5 mos.	60.6 (32-88)	83/25

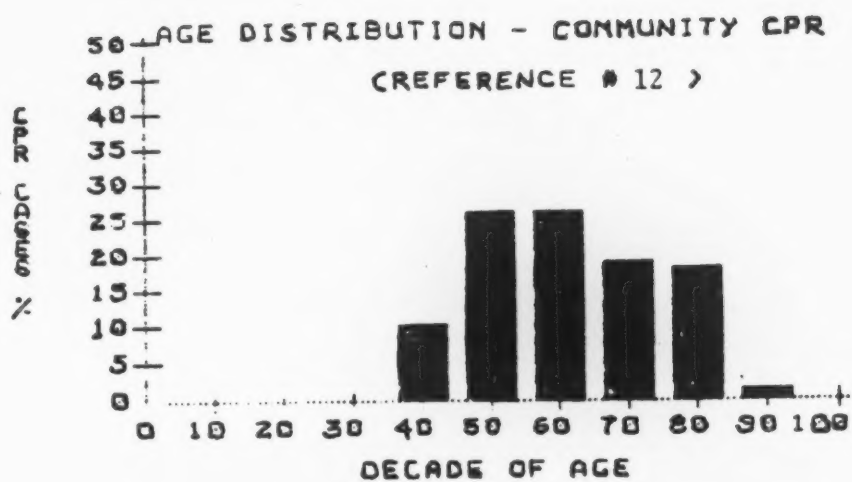
*CPR = Number of cardiopulmonary resuscitations

Hospital cardiopulmonary resuscitation reports in medical literature are summarized in Table 2. The mean age of patients resuscitated in hospital is 60 years, similar to the community patient mean, and the range of ages is also wide. A few centers provide the distribution by decade of age of patients resuscitated. Data from two EMT and paramedic resuscitation studies ^{11,12} are shown in Figure 3 and Figure 4¹². Approximately 55 percent of all patients resuscitated are >60 years, 25 percent are >70 years, and 10 percent above 80 years of age. The male/female ratio is 2.3, or equivalently 70 percent of resuscitations occur in men. Most reports do not provide information on the number of hospital beds, number of admissions per year, or the number of bed-days (days per year in which available hospital beds are occupied by a patient) and it is therefore difficult to accurately estimate the incidence of CPR from individual reports. Because the age distribution of patients in hospital at risk of cardiac arrest and likely to receive CPR is not reported, the age specific incidence rates of in-hospital CPR are not available. The best available data ^{4,22} suggest that in some hospitals approximately 1 to 2 percent of all admissions may require CPR and CPR is performed in approximately 30 percent of all in hospital deaths.

Approximately 245,000 hospital patients have cardiac arrests occur in the United States each year. This estimate is derived from reports of the number of hospital discharges each year of patients 65 years of age or older, (11,697,000 in 1982), the proportion of hospital discharges with a fatal outcome in patients 65 years of age or older (6.5 percent in 1981),²⁷ and the estimate that CPR may be performed in a third of all hospital deaths.⁴ This crude estimate of the number of cardiac arrests each year in the elderly may overestimate the number of actual resuscitations, since cardiopulmonary resuscitation may not be uniformly available for one third of all elderly patients who die in all hospitals in the United States.

000051

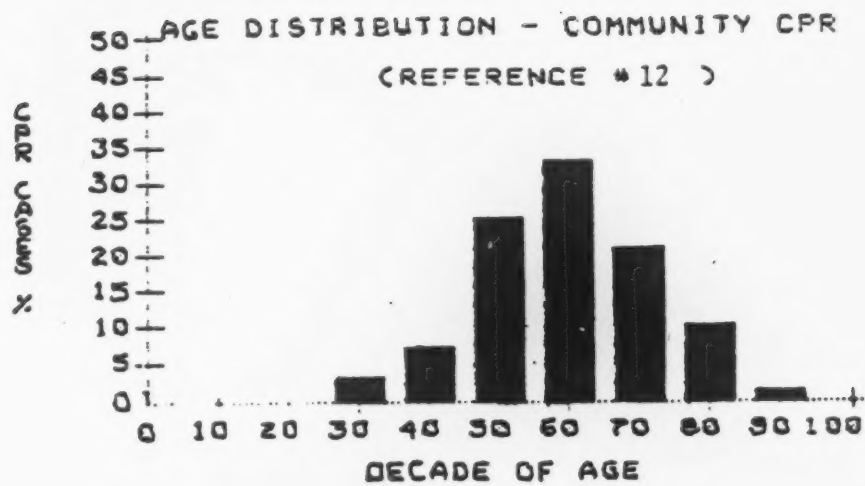
Figure 3.



Source: Eisenberg (12)

000052

Figure 4.



Source: Eisenberg (12)

Success Rate of Cardiopulmonary Resuscitation (Table 3)

The success rate of community cardiopulmonary resuscitation can be measured by the hospital admission rate of patients receiving community CPR. Community CPR has a mean success rate of 35% with individual papers reporting success rates of 23% to 44%.

One study³⁷ reports age specific success rates for community cardiopulmonary resuscitation. In this study of 346 resuscitations the highest success rate of 81% occurred in persons 50-59 years of age. The success rate was 70% in persons 60 to 69 years of age, and 40 to 50% in persons older than 70. (Table 3) The overall success rate of resuscitation in this report is higher than rates reported in other studies and suggest that the success rate of community resuscitation in the elderly is high even in the very old.

00055

Table 3 (Continued)

		<u>Hospital Discharge Rate of CPR Survivors %</u>							
		Hosp CPR	0	13	9	17	25	16	14
Bedell (N=128) (4)									
DeBard (N=214) (9)	Hosp CPR			19			39		42
Peatfield (N=357) (N=1063) (28)	MI** pts. All pts.			-		25 11	28 7	22 9	
Szczygiel (N=92) (37)	Survivor of Commun. CPR	0	0	0	40	63	81	70	40
Tweed (N=2091) (43)	Hosp CPR		22		13		13		12
									10

*EMT=Emergency Medical Technician Services

**MI= Myocardial Infarction

000056

Table 4 - Success Rate of Cardiopulmonary Resuscitation

Study	Year	Setting	# Resus	Success* %	Mean Age (Range)
<u>Hospital Resuscitations</u>					
Coskey (8)	1978	urban hospital	1155	45%	54%>65
DeBard (9)	1981	teaching hospital	1073	56%	60
Scott (33)	1981	teaching hospital	78	44%	72%>60
Bedell (4)	1983	teaching hospital	294	44%	70
Scaff (32)	1984	community hospital	300	48%	43%>70
Suljaga-Pechtel (36)	1984	teaching hospital	203	49%	70 (median=74)
<u>Community Resuscitation</u>					
Eisenberg (13)	1979	community	283	44%	
Rockswold (30)	1979	community	514	33%	- 63 (for survivors)
Eisenberg (14)	1982	community	1567	36%	65
Guzy (18)	1983	community	300	23%	65±16**

*Return of heart function

**Standard Deviation

Hospital resuscitation has a uniformly high success rate of 44 - 56 percent with most urban teaching hospitals reporting a success rate of approximately 50 percent. The success rate of CPR in smaller hospitals without a housestaff present 24 hours daily may be lower; however, data are not available on the success of CPR in other settings. Age specific success rates are reported for hospital CPR from several settings. The success of CPR is 59 percent in patients <60 years of age, 56 percent in patients 60 - 69 years, 57 percent in patients 70 - 79 years, and 52 percent in patients greater than 80 years of age.⁵ The most striking observation is that the success of cardiopulmonary resuscitation does not substantially decrease in the elderly. The fact that the success rate of CPR does not vary with age suggests that the most important prognostic factors influencing the outcome of CPR are the underlying diseases which cause the cardiac arrest and the specific circumstances of the resuscitative efforts. It further suggests that decisions to initiate resuscitation may be appropriately based more on the patients' prognosis resulting from the underlying diseases than on arbitrary age criteria. Only one study⁴ specifically mentions the presence of a hospital DNR policy, and its CPR success rate is similar to the CPR success rate of other similar institutions.

Many elderly patients are residents of nursing homes, residential communities, and other long-term care facilities. Since community ambulance services respond to nursing homes, and personnel trained to perform CPR may be more rapidly available than in other community locations, a reasonable assumption is that the success rate of CPR in these special settings approximates the rates reported for community CPR.

Several demographic, clinical, and organizational factors have been examined to determine predictors of success of cardiopulmonary resuscitation. In community CPR, a witnessed cardiac arrest, bystander initiated CPR, ventricular fibrillation as initial rhythm, short arrest time, and short resuscitation time predict a good outcome. Patients' age does not predict outcome when these factors are included in the analysis. Hospital CPR is associated with a good outcome when arrest time is short or the initial

rhythm is ventricular fibrillation. Several underlying medical conditions are associated with a poor outcome, and include sepsis, stroke, cancer, pneumonia and homebound lifestyle. When underlying medical conditions are included in analyses, age does not predict a poor outcome. The location in the hospital where the cardiac arrest occurs, (outside of the operating room) has only a small affect of the success of resuscitation. In one hospital the yearly increase in the success rate of hospital resuscitation paralleled the increase in the yearly proportion of monitored hospital beds, suggesting that the monitor, an "electrical witness" may have diminished the time between cardiac arrest and resuscitation, and thus resulted in a higher success rate.

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Table 5 - Predictors

Study	Year	Bad Outcome	Good Outcome	Not a Factor
Bedell (4)	1983	pneumonia hypertension renal failure cancer homebound life-style sepsis stroke	arrest 15 min VF	age hospital location
Linn (23)	1970	Asystole	chronic cardiac condition multiple arrests	age Physician CPR time of arrest place of arrest
Suljaga-Pechtel (36)	1984	pH 7.2✓ asystole EMD	VF or VT 70 years female	location time pre-existence of: shock coma stroke malignancy
Cummins (8a)	1984		witnessed early CPR VF 12 min to ALS	age sex
Fusgen-Summa (15)	1976	multiple pathology asystole	CPR within 4 min. CPR duration 3 min.	age # resuscitations
Eisenberg (11)	1979	12 min to definitive care	short time to CPR short time to definitive care	age sex weight

Key: EMD=electrical-mechanical dissociation; VT=ventricular tachycardia; VF=ventricular fibrillation

Causes of Arrest

The causes of cardiac arrest are difficult to ascertain since the underlying medical conditions that result in cardiopulmonary arrest are often unknown, not evaluated, or not reported. The majority of patients experiencing cardiopulmonary arrest have sudden cardiac death as a manifestation of underlying heart disease, usually significant coronary artery disease. A cardiac arrest in the community is often equated with sudden cardiac death from underlying coronary artery disease. In the majority of cases no further investigation or evaluation is performed and an autopsy is not obtained. Other causes of cardiopulmonary arrest and sudden death include cerebrovascular disease, intracranial hemorrhage, ruptured aortic aneurysm, pulmonary embolism, and poisoning. In many reports only the electrocardiographically documented heart rhythm initially present at the time of the cardiac arrest is reported and little additional information is available. Table 6 reports initial ECG rhythms and underlying medical conditions in patients experiencing a cardiac arrest.

The initial cardiac rhythm in the majority of arrests is ventricular fibrillation present in approximately 60-90% of community cardiac arrests. Ventricular tachycardia is the second most frequent rhythm. Ventricular fibrillation is the most common arrhythmia in hospital cardiac arrests, occurring in 33 to 40% of arrests. Ventricular fibrillation and ventricular tachycardia are most often the initial rhythm in cardiac arrests due to coronary artery disease, the most common cause of community cardiac arrests. The widespread use of electrocardiographic monitoring in hospital, not only in coronary and intensive care units but by telemetry outside of intensive care units, allows for early detection of arrhythmias and cardiac arrests in groups of patients who are known to have coronary artery disease or other conditions that may increase the risk of cardiac arrest. The spectrum of diseases in hospitalized patients is very different than in the community. Therefore cardiac arrests in which the initial rhythm is a rhythm other than ventricular fibrillation or ventricular tachycardia are more often seen than in community cardiac arrests.

000061

Table 6 - Causes of Cardiac Arrest

Study	Year	Setting	Initial ECG	# Resus	Co-morbid Condition
Hill (20)	1977	community arrests	MI	182	
Gudjonsson (17)	1978	community arrests	57%VF 8%Asystole	222	
Eisenberg (11)	1979	community arrests	32%VF	604	81% heart dis 4% cancer 3% neuro 3% resp 2% drowning 2% SID 2% suicide & drug OD
DeBard (9)	1981	teaching hosp	usually VF	1073	46% cardiac 22% pulmon 7% CNS 7% trauma 18% other
Eisenberg (14)	1982	community arrests	67%VF	1567	
Roy (31)	1983	community and hospital arrests	59%VF 28%VT	119	CAD
Bedell (4)	1983	teaching hosp.	33%VF or VT 27%Resp. Arr. 18%Asystole 16%EMD* 4%3 HB**	294	26% CRF 24% DM 20% pneumonia 5% CA
Pionkoski (29)	1983	community arrests	VF	565	
Tresch (41)	1984	community arrests	96%VF 1%VT 2%Asystole	139	Cardiac Dis. Cancer
Sowden (34)	1984	2 general hospitals	60%Asystole 40%VF	108	vascular disease Cancer cerebral injury

*EMD - Electromechanical disassociation

**3 HB - Third degree heart block

Survival of Patients Receiving CPR

In this study of cardiopulmonary resuscitation in the elderly, survival is reported as the fraction of the entire group of original patients experiencing CPR who are successfully resuscitated and discharged from the hospital alive. Prolonged survival following hospital discharge is also important. Many papers report survival following hospital discharge as the fraction of all patients discharged alive. Post discharge survival is reported here as the fraction of the original group of patients experiencing CPR to allow consistent comparisons and relate ultimate survival to the cardiopulmonary resuscitation.

000063

Table 7 - Survival* of Patients Receiving CPR

Study	Year	Setting	# Resus	Hosp D/C	Survival Rate		
					6 mo.	1 yr.	2 yr. +
Fusgen-Summa (15)	1976	geriatric institute		335	7%	5%	
Coskey (8)	1978	urban hospital	1155	16%			
Gudjonsson (17)	1978	urban; community	222 arrest	9%			
Rockswold (30)	1979	urban; community arrest	514	16%			
Cobb (6)	1980	urban; community arrest	1434	16%			
Scott (33)	1981	teaching hospital	78	14%			
DeBard (9)	1981	teaching hospital	1073	24%		18%	7%
Eisenberg (14)	1982	community	1567	19%	16%	15%	13%
Bedell (4)	1983	teaching hospital	294	14%			
Dohi (10)	1983	urban hospital	71	22%			
Pionkowski (29)	1983	community arrest	564	46%			
Roy (31)	1983	community and hospital arrests	119			40%	21%
Scaff (32)	1984	community hospital		300	14%	11%	8%

*Survival to hospital discharge and post-discharge survival

The results of community and hospital resuscitation are similar and shown in Table 7. The average survival rate to hospital discharge is approximately 20 percent to 25 percent of all patients who experience a cardiac arrest. Post discharge survival rates at one year are in the range of 10 to 20 percent. Hospitals reporting higher rates usually describe a selected group of patients, such as patients with VF arrests only or patients referred for evaluation for obstructive cardiomyopathy. Age specific long term survival rates for elderly patients experiencing resuscitation are not known.

Patients who experience a cardiac arrest may be at risk for recurrent cardiac arrest following successful resuscitation and survival to hospital discharge. Table 8 suggests that recurrent sudden cardiac death is the most likely cause of death in survivors of cardiopulmonary resuscitation.

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Table 8 - Cause of Death in Patients Discharged Alive

Study	Year	# Resus.	# D/C Alive	Deaths	Cause	
Baum (3)	1974	886	146	43	SCD*	
Rockswold (30)	1979	514	83	13/47 in 13 mos	SCD	
Eisenberg (14)	1982	1567	302	102	ASHD valvular H.D. CNS dis other	89% 5% 3% 3%
Bedell (4)	1983	294	41	8 in 6 mos.		
Agnew (2)	1983	65	31	7	recurrent VF	
Suljaga-Pechtel (36)	1984	226	30	9 in 6 mos.		

*SCD=sudden cardiac death

Recent Trends in Success Rate and Survival Rate

The success rate of CPR gradually increases in the early part of the decade of the 1970's. Most recent reports suggest that the success rate of CPR has reach a plateau. Figure 5 shows the yearly trend in CPR success from those institutions reporting the results of community CPR in consecutive years. Figure 6 demonstrates a similar plateau in the yearly trend in the hospital discharge rate of patients experiencing CPR.

Functional Status of Patients Successfully Resuscitated

The functional status of patients resuscitated from cardiopulmonary arrest depends on the extent of anoxic injury to the brain sustained as a result of the interruption of blood flow to the brain. The data on functional status of patients resuscitated is limited. Many studies report a high incidence of neurologic injury but careful determination of residual neurologic deficits is not available. The reported range of new neurologic deficits is wide, from approximately 1-5% to as high as 25 - 40%. Although the elderly may be more vulnerable to the injury of cerebral anoxia, there is no data on the age specific incidence of new neurologic deficits in the elderly resulting from cardiopulmonary resuscitation.

Among 276 survivors of community CPR in one study,¹⁴ 91% of survivors were discharged home and 9% were discharged to a nursing home. Of those discharged home, 27% resumed full-time work and 7% part-time work.

Among 41 survivors of hospital CPR 25% were newly institutionalized, 50% newly homebound, and 25% newly retired.⁴

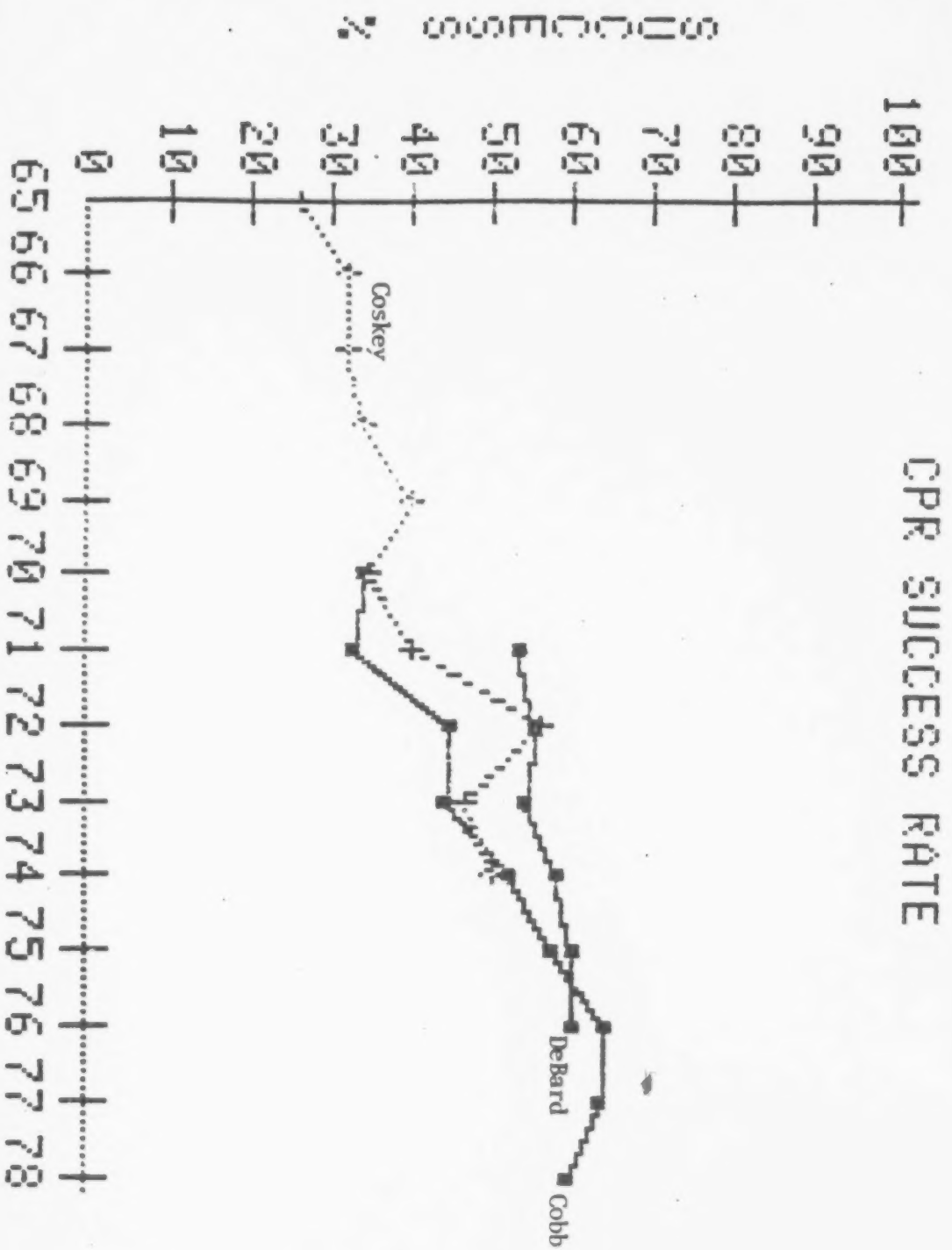
Since anoxic injury to the brain is correlated with longer time to BLS and ALS as well as with duration of CPR, the factors which predict success of CPR and survival to discharge are also likely to be important as predictors of functional status.

As medical progress is made with the introduction of new medications, techniques and technologies, it is inevitable that there will be diseases of medical progress and iatrogenic injuries. Complications of cardiopulmonary resuscitation include rib fracture, pneumothorax, fractured teeth, ruptured stomach, bone marrow embolism, and emphysematous cholecystitis. There is little data available on the incidence of these injuries, and therefore at present it can not be determined if they are more common in the elderly.

Table 9 - Yearly Trends

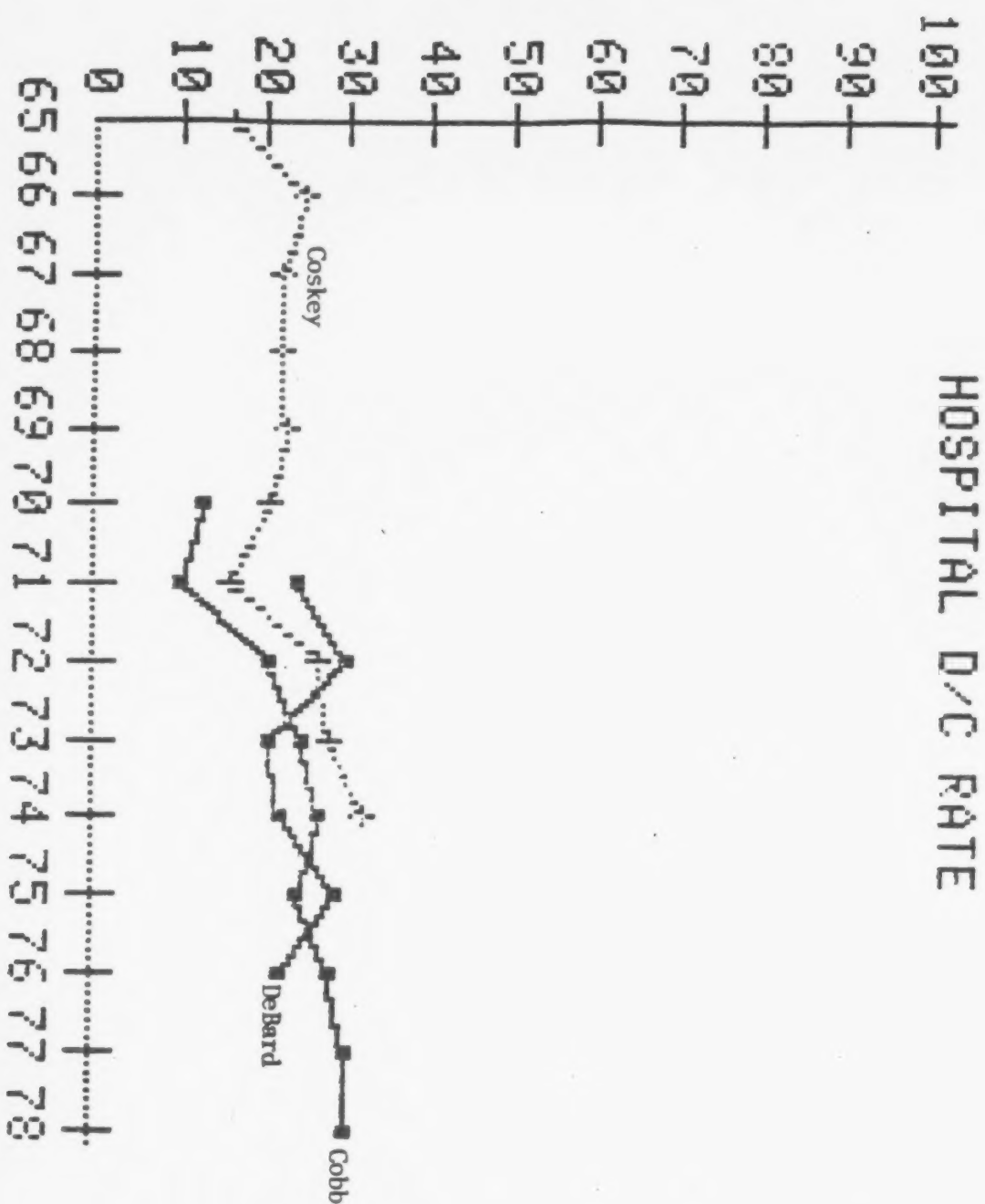
Study	Comments	1960-62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79
CPR Success %																			
Cobb (7)	VF only										34	33	45	44	52	57	64	63	59
Coskey (8)	Hosp CPR				26	32	32	34	40	35	40	56	47	50					
DeBard (9)	Hosp CPR										53	55	54	58	60	60			
Patients Discharged %																			
Cobb (7)	VF only									13	10	21	25	27	27	24	28	30	30
Coskey (8)	Hosp CPR				16	25	22	22	23	21	16	27	28	32					
DeBard (9)	Hosp CPR										24	30	21	22	29	22			
Lemire (22)	Hosp CPR	14	18	14	14	24	25	19	22										
Tweed (43)	Hosp CPR																		
	Comm CPR												18	19	18	15	17		
													7	7	6	8	5		

Figure 5.



0200000

Figure 6.



YEAR

Table 10 - New Neurologic and Other Medical Problems

Study	Year	Setting	# Resus.	Conditions	N or %
Agnew (2)	1983	urban hospital	65	permanent brain damage	13%
Bedell (4)	1983	teaching hosp.	294	coma	52 (18%)
Coskey (8)	1978	urban hospital	1155	neurologic defect	42 (4%)
Dohi (10)	1983	urban hospital	78	pulmonary edema	20 (26%)
Longstreth (24)	1983	teaching hosp.	459	coma neuro. deficit	180 (39%)
Sowden (34)	1984	2 acute gen hospitals, Engl.	108	Cerebral impairment memory loss	1 (.9%)
Thomassen (39)	1979	teaching hosp.	181	coma 7 days	33 (18%)
Tresch (41)	1984	teaching hosp.	139	coma neuro. impairment	3 (2%) 7 (5%)
Rockswold (30)	1979	teaching hosp.	514	hypoxic brain damage	34 (20%)

Resources Needed

Because an unsuccessful cardiopulmonary resuscitation is a patient's death, the survivors of resuscitation consume more resources than nonsurvivors. Detailed analyses of resources needed for survivors of cardiopulmonary resuscitation are not available, and therefore detailed estimates for resources needed in elderly are not available. Virtually all survivors of resuscitation are admitted to hospital intensive care units. The average hospital length of stay for patients with CPR is 12 days with 4 days in an intensive care unit.³⁷ Survivors of cardiopulmonary arrest are hospitalized nearly 3 weeks (20 days) longer than nonsurvivors.⁴ The best available data on the hospital and intensive care unit length of stay shows no differences in ICU or hospital length of stay for patients 55 - 64 years of age, 65 - 74 years of age, and patients 75 or older.⁵ In another report 78 percent of patients admitted to medical ICU for cardiopulmonary arrest require major intervention such as ventilation, dialysis, invasive hemodynamic monitoring or other invasive treatment.

An undocumented but important and costly resource for a large fraction of patients successfully resuscitated is coronary artery bypass graft surgery (CABG). Although survivors of cardiac arrest may not be a large fraction of all patients receiving coronary artery bypass grafts, the majority of patients who survive a cardiac arrest have coronary artery disease and a substantial portion may have indications for CABG. Detailed information is not available, and age specific information on the need for CABG in the elderly is needed.

Complications of CPR

Cardiopulmonary resuscitation is a vigorous procedure in response to a life-threatening medical emergency. Since delay reduces the effectiveness of CPR, the emergent use of routinely safe procedures in circumstances with limited personal, equipment, and facilities results in a higher complication rate than is associated with most elective medical procedures. CPR requires an open airway, effective ventilation by

face mask or endotracheal tube, closed chest compression to provide blood flow, and often access to large blood vessels in the neck, chest or groin. The medical problems of CPR will have an inherent risk of complications.

In contrast to neurologic deficits which result from decreased blood flow to the brain during the cardiac arrest, other injuries and complications may occur as a result of the resuscitation. In an autopsy series of 70 non-survivors of cardiopulmonary resuscitation, 40% of patients had at least one CPR-related abnormality and 11% had more than one complication. The most common complications found were fractured ribs, fractured sternum, bone marrow emboli to lungs and mediastinal bleeding.⁴⁵ The incidence of CPR related injuries in survivors of CPR may be as high as 32%.⁴⁴ Although the clinical significance of some findings in autopsy series is uncertain, it is likely that a substantial fraction of survivors of CPR experience some morbidity as a result of a resuscitation. It is currently not possible to determine how often unsuccessful resuscitations have failed as a result of a complication from the attempted resuscitation rather than from the underlying condition of the patient.

Conclusions

The medical literature can provide information on the utilization and outcomes of cardiopulmonary resuscitation in the elderly provided it is cautiously interpreted and critically evaluated. A substantial amount of information on the utilization and outcomes of CPR is not easily available and age specific information applicable to the elderly population is rare. Nevertheless, a general pattern does emerge from the literature and is summarized below:

- * Approximately 75,000 community and 245,000 hospital cardiopulmonary arrests occur in the United States each year.

- * Hospital resuscitation occurs in 1-2% of all admissions, 30% of all hospital deaths, and can produce a 6% reduction in hospital mortality.
- * The success rate for cardiopulmonary resuscitation is approximately 35% in community resuscitation and 50% in hospital resuscitation.
- * Approximately 15% of all patients resuscitated survive hospital discharge and are alive 6-12 months following the arrest.
- * The majority of cardiac arrests are due to coronary artery disease; the most common rhythm present is ventricular fibrillation.
- * As many as 50% of cardiac arrests occur in the elderly and the success rate and survival rate do not decrease with advanced age.
- * A substantial portion of patients resuscitated experience new neurologic injury but the extent of permanent neurologic deficits is difficult to ascertain.
- * Survivors of resuscitation require increased medical resources; 80% require major interventions and their hospital stay may be 3 weeks longer than non-survivors.
- * The paucity of available data suggests a need for uniform reporting of data and collection of more detailed information on the utilization and outcomes before specific policy on CPR in the elderly can be formulated.

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III. Cost of CPR

There is no published or readily available information that describes the cost of cardiopulmonary resuscitation. The only two relevant reports are from one study of intensive care at the Massachusetts General Hospital in Boston and present the total hospital charges for intensive care patients.^{4,19} One of these reports, by Thibault et al., identifies patients admitted to intensive care following a cardiopulmonary resuscitation (CPR) but does not identify the patients by age.¹⁹ The companion report by Campion, gives age-specific patient data but does not identify those who had had resuscitation.⁴ There are no available models that project the national annual cost of CPR. There are no cost-benefit or cost-effectiveness studies of in-hospital CPR.

Information is contained in several hospital research data sets that could be further analyzed to give information relevant to cost of CPR for the elderly. The Medicare program codes "cardiac arrest" as DRG 129. The medical record codes "sudden death syndrome" as IGDA-9798.1, but typically does not indicate whether CPR was used or, if used, whether it was successful. Hospitals post charges for CPR-related services and procedures, and send patients and their insurers bills that include these charges. The most surprising finding of this study is that, in spite of these facts, the cost of a CPR event is not known. The reason is three-fold: existing medical record systems do not code CPR, an accurate description of the clinical activities which make up a CPR event do not exist, and charges for CPR services are inextricably mixed in the total hospital bill.

In order to estimate the cost of CPR we must specify the exact activities or events that we refer to as CPR. CPR may take place if cardiac or pulmonary arrest occurs and is recognized. The resuscitation itself may occur in the community, that is, out-of-hospital, the hospital emergency room, at the bed of a hospitalized patient, or in an intensive care unit (ICU). In each of these situations the cost may be substantially different. The activities which generate costs that need to be considered are: pre-hospital care; the resuscitation event itself; post-resuscitation intensive care; and post-

intensive care hospitalization. Hospitalization charges for the same services may vary 100 percent or more with hospital type and location.

Finally, in order to discuss the cost of CPR we must specify the cost to whom: the hospital that provides the service; the patient and/or the insurer; or the health care economy of the nation as a whole. As we will show, the cost to the hospital for a CPR event is not known. The cost to the patient or insurer may be approximated by the total hospital charges for an admission that involves CPR. The cost to the nation might be estimated by the product of the number of in-hospital CPRs and the average cost or charges for CPR hospitalizations. In this report, we examine information that relates to these three sorts of costs.

Available Information

Published reports relevant to questions of the cost of CPR in the elderly were retrieved by: a) Medline and other data-base search, b) review of reference lists and bibliographies and c) telephone query of research scientists in the field. The methodology and the quality of the research in the studies cited was not evaluated as the relevant data are primarily descriptive and not experimental studies or conclusions. The relevant papers are listed in Table 1 with a brief summary of the type of financial information they contain. Most of these papers are concerned with the costs of intensive care as estimated by hospital charges.^{4,5,7,8,13,14,15,18,19,21} In only one paper is information given about total hospital charges for CPR.¹⁹ A second paper⁴ examines intensive care unit (ICU) charges by age: 55-65, 66-75, over 75 years old. These two papers are summarized in Table 2. Both of these studies are from a single data base at the Massachusetts General Hospital (MGH). The MGH group has available the data to examine the cost of care of CPR patients admitted to the MGH intensive care unit by age, sex, comorbidity, and complication, and further research on this data could be commissioned.

Out-of-Hospital Resuscitation

A small literature exists about the costs and cost effectiveness of programs of out-of-hospital resuscitation.^{1,6,10,14,20} This literature, which deals in large part with evaluation of the program sponsored by King County in Washington State, is summarized in Table 3. It should be noted that the costs are principally program costs of establishing and maintaining the emergency medicine services, transportation, and training. It is difficult to apportion the purely health care or medical costs of these programs. They are typically funded from a variety of sources: third parties and federal, state, and local governments. Secondly, the King County program with its large component of trained lay persons may not be reproducible in other communities.

Cardiac arrest may occur in presumed healthy or heart-diseased person during their daily activities, or as in "dropping dead." Goldman and others estimate that three out of five or 60 percent of all deaths from acute myocardial infarction occur outside of the hospital.¹¹ A number of interventions have been studied which are directed at reducing out-of-hospital deaths of persons who experience cardiac arrest: training police and firemen in CPR, community-wide lay training in CPR, development of emergency medical technician (EMT) programs that offer both CPR and basic life support and paramedic or mobile CPR units that offer rapid access to advanced life support services: defibrillation, intubation, IV drug, etc. More than 300 paramedic or advanced life support programs had been undertaken in the U.S. by 1980. The effectiveness of these programs has been recently reviewed by Weinstein and Stason.²²

The cost and cost-effectiveness of prehospital CPR has been examined in a small number of studies which are summarized in Table 3. Only one of the investigations²⁰ limits the study population to heart-disease related cardiac arrests and excludes trauma and electrocution. None of the studies includes break-down by age. The 1973 study of mobile coronary care units by Acton of the Rand corporation is one of the first examples of a medical cost-effectiveness investigation.¹ He estimated a marginal cost per life

save of \$4,300 in 1970 dollars (\$18,000 in 1984 dollars). Urban et al. use the experience of the King County, Washington program to estimate a cost of \$43,000 per life saved in 1978 dollars.²⁰ Cretin used a biological model of the life history of cardiac disease to estimate the cost per life-year saved by mobile coronary care units as between \$3,140 and \$6,100 in 1979 dollars.²⁰ The authors examined several discount rates. In estimating a person's future earnings for cost-effectiveness calculations, such earnings must be decreased or discounted by some amount, the discount rate, as cash in hand in the present is worth more than the same amount realized in the future. Cretin's study used a range of discount rates and produced a corresponding set or range of cost estimates.

The studies summarized in Table 2 are in fact, not directly comparable because of differing assumptions: discount rates, life expectancy of surviving cardiac arrest victims, ambulance response times in urban and suburban communities, and the number of ambulance runs to a non-myocardial infarction case or "false alarm" compared to runs to true actual myocardial infarction cases with CPR. Another important issue discussed below is whether to include in the cost the subsequent hospitalizations and intensive care of the out-of-hospital CPR survivors. No studies have distinguished costs of out-of-hospital CPR in urban and suburban settings. In summary, the cost per life saved or death averted by pre-hospital CPR programs can only be estimated in broad ranges. Urban, Bergner and Eisenberg suggest \$6,000 to \$42,000 as such a range.²⁰ These estimates include both successful and unsuccessful CPR cases (See Chapter II).

Why the Costs Cannot Be Estimated

The most surprising result of this investigation is the conclusion that the cost of the in-hospital CPR event for elderly persons is not known. It has not been measured or estimated. To do so is not a trivial exercise and will require significant new research.

The medical record codes CPR as ICDA (ICD-9-CM) 798.1 "sudden death syndrome". The Medicare program codes CPR as DRG #129, "cardiac arrest". Hospitals

post charges for services, procedures and ancillaries used during the CPR event, and send bills that include these charges to patients and their insurers. How can it be that the cost of CPR is not known? The answer is in three parts: 1) existing medical information systems do not uniformly encode or identify CPR as a diagnosis or a procedure, 2) the inputs to the CPR event (professional services, tests, drugs, equipment and procedures) have not been systematically described, and 3) charges for these CPR inputs are inextricably buried in the hospital bill and cannot be aggregated as a single "cost" of an episode of CPR.

Cardiopulmonary resuscitation (CPR) is the set of medical procedures used to provide effective breathing and circulation in a person who has a cardiac arrest (See Chapters I & II above). The resuscitation event begins with the recognition of cardiac arrest. CPR may last a few minutes to several hours, most commonly 30-60 minutes. A CPR, if unsuccessful, ends in death; if successful, CPR ends with a stable pulse and blood pressure. Neither the duration nor the precise content of CPR has been systematically studied. All successful CPR patients are hospitalized and all are treated initially in an intensive care unit.

Secondly, although narrative descriptions of the CPR event, like that in Chapter II, are available, the CPR event has not been systematically described. How many minutes of work by what kinds of people are involved? What exact procedures are used: intubation, ventilation, defibrillation, cannulation, packemaker insertions etc. What drugs are administered? What laboratory and cardiac tests are performed? Each of these items is an input to the CPR event. Nowhere in the scientific literature have these inputs been measured during actual CPR. How these inputs might vary between different types of hospitals, age or sex of the patient, or underlying disease state is similarly not known. This information cannot be reasonably estimated, even by experts, and if needed must be obtained by specific new research investigations.

Finally, if a patient has a cardiac arrest, doesn't the hospital send a bill for CPR and the related services and couldn't the cost of CPR be estimated from these charges? In fact it cannot. Just as the CPR event and its inputs are embedded in the hospital stay, so the CPR-related charges are embedded in the bill. The hospital billing process is initiated when periodically, every several hours or every several days, a clerk on the patient's ward enters in the chart, usually through a computer terminal, a charge code or identification number for each test, service and procedure that the patient has had since the time of the last charge entry. The billing system multiplies this code by the dollar charge associated with that code, resulting in a list of charges which become the bill. The charges are usually but not always listed in rough chronological order; but it is none-the-less impossible to examine a bill or a list of charges of a CPR patient and identify which charges are for the CPR-related activities.

To illustrate this point the complete set of hospital charges for a typical CPR patient is appended. It is impossible to identify those items that relate to the CPR event and those that resulted during hospitalization before and after CPR. To know the cost of the CPR event with any precision one would need to observe the event, record the inputs, determine from the bill which of the inputs used had, in fact, generated charges, and sum these charges to get the cost of the specified CPR event.

One very rough attempt to estimate the direct cost of the resuscitation event has been described in the literature is summarized in Table 4.¹³ The result cannot be generalized and is presented only to illustrate the problem. The estimate of \$366 per event is not based on direct observation of the inputs to the CPR activity. Rather, Hahn and co-workers totalled the average annual cost to the hospital of the CPR committee and certain of the hospital charges for resuscitation and divided by the annual number of CPRs to get the cost per event.

In-hospital Resuscitation

In-hospital Resuscitation

Patients, if alive at the conclusion of the resuscitation, are in almost all cases cared for in an intensive care unit. Thibault et al. in the only relevant published report note that the average CPR patient on their service at the Massachusetts General Hospital stayed in the intensive care unit 4.3 days out of a total stay in the hospital of 12.2 days.¹⁹ For these 41 patients admitted to the ICU following resuscitation the average total hospital charges were \$7,235. Median total charges for all hospital services were \$4,557. (See Table 2). In a second study from the same hospital the charges were broken down by age but not by morbidity.⁴ That is, in the second study we know the patients' age but cannot identify the patients who have had CPR. The Thibault study identified ICU patients who have had CPR but does not break them down by age. Once admitted to the ICU/CCU older patients were more likely to receive major life support interventions such as mechanical ventilation and were less likely to survive.

The most important finding is that elderly patients had no longer mean lengths of stay and no greater mean total hospital charges than younger patients. This suggests that the total hospital charges of elderly patients who have had resuscitation may not be greatly different from the cost for adults of all ages. As all patients who receive in-hospital CPR are then sent to the ICU, the total hospital charges for such patients might be considered a proxy for the cost of in-hospital CPR. Thibault's number of \$7,235 for 41 adult patients of all ages at one Boston teaching hospital is the only available estimate.

Elderly hospital intensive care survivors returned to their preadmission living situations but did not regain their preadmission activity level. Patients admitted to an ICU/CCU fall into one of two categories: those needing active intervention and those needing only surveillance. In the Massachusetts General Hospital studies the mean hospital bill for those patients requiring little or no intensive therapy was less than \$2,000. Of ICU/CCU admissions requiring active intervention CPR patients had mean hospital bills

of \$7,235; higher than chronic obstructive pulmonary disease (\$4,499) and diabetic keto-acidosis (\$17,201). These examples are given to illustrate the range of charges. It has been pointed out that within the ICU charges there is cross-subsidization by the low cost of the high cost cases. That is, charges for the low cost cases exceed cost while charges may be less than cost in the intensive case such as sepsis and respiratory failure.

Models

What is the financial burden to our country of the cardiopulmonary resuscitation of persons over 65 years of age. To answer the question we must know both the number of such resuscitations performed and the cost of each. The simplest model for such a projection is summarized in Table 5. The data needed to exercise this model and make a reasonable estimate of such costs does not exist, as suggested in the Table.

First, how many cardiac arrests occur in persons over 65 per year? In one sense, in every death that occurs there is a cardiac arrest; that is, we are not dead till our hearts stops. Therefore, everyone who dies is at risk of cardiac resuscitation. Viewed in this way, cardiac arrest is the final common pathway from life to death by any cause. However, most studies of resuscitation deal with cardiac arrest in persons with known or presumed heart disease, or more specifically, acute myocardial infarction. The incidence of arteriosclerotic heart disease is well studied. The national ischemic heart disease mortality rate has declined steadily over the 1968 to 1978 decade, from over 900 to less than 800 per 100,000 persons. The rate of hospital admissions for myocardial infarction was 632 per 100,000 in 1978-79 and the in-hospital mortality rate was 22%. In persons 60-69 years of age, the age specific hospital admission rate was 795 in 1979 while the rate was 1376 for persons over 70.^{11,22}

The number of hospital cardiac arrests in persons over 65 has been estimated in Chapter II, above, to be 245,000 per year. This number could be used to estimate the number of in-hospital CPRs performed annually on persons over 65, if we knew the

fraction of over-65 hospital cardiac arrests in which resuscitation is attempted. The fraction of cardiac arrest patients who receive DNR orders or who are not resuscitated for other reasons is not known. Cardiac arrest have two outcomes: death and survival. Death results in the instance of either no CPR or unsuccessful CPR. We know the rate of success in attempted CPR but not as a fraction of all cardiac arrests.¹⁷

Absent such information about the number and costs of CPR, the computation suggested in Part B of Table 5 is proposed as a very rough approach to an estimate of the annual national cost of CPR in persons over 65. If 245,000 cardiac arrests occur annually in persons over 65, and if CPR is performed in the majority of those arrests, and if the success rate is 50%, and if the cost per case is \$7,235, then, multiplying, the total (national) annual cost of in-hospital CPR in the elderly is \$886 million.

Summary

. The cost of an episode of resuscitation is not known for any class of patients because the inputs to the CPR event have not been described.

. The total costs of a hospitalization that includes an episode of CPR is a proxy for the cost of in-hospital CPR but studies of hospital cost or charges for CPR patients by age have not been performed.

. The only published proxy for the per case cost of CPR in the elderly is Thibault's 1980 report of average total hospital charges of \$7,235 for adult patients admitted to the ICU following resuscitation.

. If 245,000 CPRs are attempted annually on elderly patients in-hospital with a success rate of 50% at a cost of \$7,235 per case, a rough estimate of the annual national cost of CPR in the elderly is \$886 million.

. Crude estimates of national costs of CPR ought not be used to influence resource allocation decision-making.

Table 1. Reports that Contain Information on the Cost of CPR.

<u>Study</u>	<u>Year</u>	<u>Type of Cost Information</u>
Campion (4)	1981	Mean & median hospital charges by age but not by diagnosis in elderly (greater than 55 y.o.) patients receiving ICU/CCU care. (n= 1701)
Thibault (19)	1980	Mean and median hospital charges by diagnoses (e.g., CPR), but not by age, of ICU/CCU patients (n=74)
Cullen (8)	1984	Mean and range of total hospital charges of ICU patients (n=189) No data on age or CPR. Average charges \$22,000 per patient.
Cullen (7)	1976	Mean and range of total hospital charges of ICU patients. No data on age or CPR.
Chassin (5)	1982	Total six month medical care costs for 489 MICU patients. No data on age or CPR.
Hahn (13)	1979	Estimated direct cost of 146 CPR's at Univ. of CA at San Francisco 1977 as \$366. No age information.
Knaus (15)	1983	A policy paper presenting aggregate estimated resource use & cost for 1,987 ICU admissions over 27 months using an activity analysis resource measure. No data on age or CPR.
Wagner (21)	1983	Charges and cost estimates of two types of ICU patients (Coronary artery bypass graft & Brain Surgery) suggesting cross subsidies. No age or CPR information.

Table 2. Charges for In-Hospital Resuscitation

<u>Study</u>	<u>Year</u>	<u>Region</u>	<u>Age</u>	<u>Total* Charges for Hospitalization</u>
Campion (4)	77-79	Boston MA	55 n=36	\$5,382- 5,862 (range)
Thibault (19)	77-79	Boston MA MGHosp	10-99 n=74	\$7,235± 1,544(SEM) 4,557 (median)

*These amounts are the total hospital bill, or charges, for elderly patients who have had medical intensive care (Campion) or patients who have had medical intensive care following a CPR event (Thibault 19). The charges cannot be compared to the cost estimates of Table 3.

Table 3. Costs of Out-of Hospital Resuscitation

<u>Study</u>	<u>Year</u>	<u>Region</u>	<u>Information</u>	<u>Estimate</u>
Acton (1)	1973	Los Angeles CA	Survey of people's willingness to pay for saving the life of an MI victim- Also cost per life saved	\$48,000 (1970) \$4,300 (1970)
Crétin (6)	1977	Los Angeles CA	Biologic life history model. 8% discount rate	\$5,400 (1975)
Eisenberg (10)	1984	-	Marginal cost/life saved	\$12,000 (1981)
Urban (20)	1981	Seattle WA	Cost per death averted in 1,035 cardiac arrests due to heart disease receiving CPR.	\$42,358 (1978)

*These amounts are estimates of the costs, not charges, of the services per life saved on death averted. No charges are involved in out-of-hospital resuscitation as patients are not billed for the service. Emergency medical services (EMS) like police or fire services are government supported programs.

Table 4. An Estimate of the Direct Costs of the CPR Event*

<u>Category and Units of Expense</u>	<u>Cost per Year (\$)</u>
<u>Personnel</u>	\$ 3,299
MD (3x\$9.60, 2 HO, 1 attending)	
RN (2x\$8.50)	
Other	
<u>Physician Professional Fee</u>	-
Drugs (\$50/case)	7,300
Supplies (IV, Airways) (\$20/case)	2,930
Inhalation Therapy	-
<u>Procedures</u>	
Defibrillation	-
Intubation	-
<u>Equipment</u>	34,488
Depreciation (5 yrs)	
<u>CPR Committee (10 members at 2 hours/month)</u>	5,450
<u>Training</u>	
Total Direct (per year)	<u>\$53,458</u>
Cost per CPR Event	366

*from Hahn et al. Western J Med 1979; 131:344-348

Table 5. Estimation of the Annual Cost of CPR for the Elderly

A. Information Needed to Estimate the National Annual Cost of CPR in the Elderly*

(1) Annual National Cost	=	(2) # of All CPRs	x	(3) Cost per Episode of CPR
(2) # of All CPRs	=	(4) # of Pre- Hospital CPRs	+	(5) # of In- Hospital CPRs
(4) # of Pre- Hospital CPRs	=	(6) All Community Resuscitations	-	(5) Non-Cardiac & Non-Elderly Resuscitations
(3) Cost per CPR Episode	=	(8) Cost of Pre- Hospital CPR for + Cardiac Arrest in the Elderly	+	(9) Cost of Hospital CPR for Cardiac Arrest in the Elderly

* The values of items (4) through (9) are not known.

B. Estimating the Annual National Cost of CPR from Thibault's Total Hospital Charges of Resuscitated Elderly Persons

(1) Annual National Cost	=	(2) Total Hospital Charges for a x Resuscitated Adult	(3) Annual # of Arrests in x Persons >65 Years Old	(4) Success Rate
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$$(1) = (2) \$7,235 \times (3) 245,000 \times (4) 0.5^* = \$886 \text{ million}$$

* 50% Success Rate of In-Hospital CPR

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Appendix

Sample hospital charges for a patient who had an in-hospital resuscitation.

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

16:03 TUESDAY, AUGUST 20, 1985

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DBS	CODE	DESCRP	CHARGES
1	0003702	ANES. 1/2 HR. LESS T	480.00
2	0003702	ANES. 1/2 HR. LESS T	445.00
3	0008401	D6 IC DSC MEDICINE	895.00
4	0010017	CHEST - P/A AND LATE	71.00
5	0010017	CHEST - P/A AND LATE	71.00
6	0010017	CHEST - P/A AND LATE	71.00
7	0010028	ESOPHAGUS	145.00
8	0010095	CHEST - SINGLE VIEW	59.00
9	0010095	CHEST - SINGLE VIEW	59.00
10	0010095	CHEST - SINGLE VIEW	59.00
11	0010095	CHEST - SINGLE VIEW	59.00
12	0010095	CHEST - SINGLE VIEW	59.00
13	0010095	CHEST - SINGLE VIEW	59.00
14	0010095	CHEST - SINGLE VIEW	59.00
15	0010095	CHEST - SINGLE VIEW	55.00
16	0010095	CHEST - SINGLE VIEW	55.00
17	0010095	CHEST - SINGLE VIEW	59.00
18	0010095	CHEST - SINGLE VIEW	59.00
19	0010106	EXAM AT BEDSIDE OR 0	54.00
20	0010106	EXAM AT BEDSIDE OR 0	54.00
21	0010106	EXAM AT BEDSIDE OR 0	54.00
22	0010106	EXAM AT BEDSIDE OR 0	54.00
23	0010106	EXAM AT BEDSIDE OR 0	54.00
24	0010106	EXAM AT BEDSIDE OR 0	54.00
25	0010106	EXAM AT BEDSIDE OR 0	54.00
26	0010106	EXAM AT BEDSIDE OR 0	54.00
27	0010106	EXAM AT BEDSIDE OR 0	50.00
28	0010106	EXAM AT BEDSIDE OR 0	50.00
29	0010106	EXAM AT BEDSIDE OR 0	54.00
30	0010106	EXAM AT BEDSIDE OR 0	54.00
31	0010106	EXAM AT BEDSIDE OR 0	54.00
32	0010106	EXAM AT BEDSIDE OR 0	54.00
33	0010106	EXAM AT BEDSIDE OR 0	54.00
34	0010106	EXAM AT BEDSIDE OR 0	54.00
35	0010106	EXAM AT BEDSIDE OR 0	50.00
36	0010106	EXAM AT BEDSIDE OR 0	50.00
37	0010106	EXAM AT BEDSIDE OR 0	50.00
38	0010150	ABDOMEN SINGLE VIEW	85.00
39	0010150	ABDOMEN SINGLE VIEW	85.00
40	0010150	ABDOMEN SINGLE VIEW	79.00
41	0010150	ABDOMEN SINGLE VIEW	85.00
42	0010150	ABDOMEN SINGLE VIEW	85.00
43	0010150	ABDOMEN SINGLE VIEW	85.00
44	0010150	ABDOMEN SINGLE VIEW	85.00
45	0010150	ABDOMEN SINGLE VIEW	85.00
46	0010150	ABDOMEN SINGLE VIEW	85.00
47	0010150	ABDOMEN SINGLE VIEW	79.00
48	0010150	ABDOMEN SINGLE VIEW	79.00
49	0010150	ABDOMEN SINGLE VIEW	79.00
50	0010239	CT BRAIN SCAN--PREPO	581.00
51	0010670	C. T. BRAIN SCAN WITH	431.00

000101

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

16:03 TUESDAY, AUGUST 20, 1985

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IDENT=03695301

OBS	CODE	DESCRP	CHARGES
52	0016609	SUCTION-GASTRIC, PORT	40.00
53	0016610	SUCTION-ORAL(DAILY U	30.00
54	0016610	SUCTION-ORAL(DAILY U	30.00
55	0016610	SUCTION-ORAL(DAILY U	30.00
56	0016619	RESTRAINTS, BODY	51.00
57	0016619	RESTRAINTS, BODY	51.00
58	0016619	RESTRAINTS, BODY	51.00
59	0016650	KIT HYPERALIMENTATIO	15.00
60	0016721	SET, STITCH	26.00
61	0016811	KITS, SUCTION CATHETE	20.00
62	0016811	KITS, SUCTION CATHETE	20.00
63	0016811	KITS, SUCTION CATHETE	20.00
64	0016811	KITS, SUCTION CATHETE	40.00
65	0016811	KITS, SUCTION CATHETE	40.00
66	0016811	KITS, SUCTION CATHETE	20.00
67	0016811	KITS, SUCTION CATHETE	20.00
68	0016812	SUCTION-CHEST, PLEUR-	86.00
69	0016812	SUCTION-CHEST, PLEUR-	86.00
70	0016826	TRAY, LUMBAR PUNCTUR	29.00
71	0016852	TUBE, DUO/INDWELL	23.00
72	0016852	TUBE, DUO/INDWELL	69.00
73	0016898	ADMISSION KIT	11.00
74	0016898	ADMISSION KIT	11.00
75	0016912	SODIUM CHLOR IRRIG 9	5.00
76	0016912	SODIUM CHLOR IRRIG 9	10.00
77	0016912	SODIUM CHLOR IRRIG 9	5.00
78	0016912	SODIUM CHLOR IRRIG 9	10.00
79	0016912	SODIUM CHLOR IRRIG 9	5.00
80	0016912	SODIUM CHLOR IRRIG 9	5.00
81	0016914	STERILE WATER FOR IR	5.00
82	0016914	STERILE WATER FOR IR	5.00
83	0016958	MATRESS, EGGRATE	23.00
84	0016974	CENTRAL SIL	21.00
85	0016978	PALL-FILTERS	25.00
86	0016979	DIAL-FLO	13.50
87	0016979	DIAL-FLO	27.00
88	0016979	DIAL-FLO	13.50
89	0016979	DIAL-FLO	13.50
90	0016979	DIAL-FLO	13.50
91	0016979	DIAL-FLO	27.00
92	0016979	DIAL-FLO	27.00
93	0016979	DIAL-FLO	13.50
94	0016979	DIAL-FLO	13.50
95	0016979	DIAL-FLO	13.50
96	0018510	STANDARD 12 LEAD E.K	39.00
97	0018510	STANDARD 12 LEAD E.K	39.00
98	0018510	STANDARD 12 LEAD E.K	39.00
99	0019020	EEG ROUTINE	80.00
100	0021003	RECOVERY ROOM 2HR LE	206.00
101	0022702	OPER ROOM-LESS THAN	875.00
102	0022702	OPER ROOM-LESS THAN	810.00

000102

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
 DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
 JULY 1984 - DECEMBER 1984

16:03 TUESDAY, AUGUST 20, 1985

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IDENT=03695301

OBS	CODE	DESCR	CHARGES
103	0024247	BLOOD GAS ANALYSIS	55.00
104	0024247	BLOOD GAS ANALYSIS	55.00
105	0024247	BLOOD GAS ANALYSIS	55.00
106	0024247	BLOOD GAS ANALYSIS	55.00
107	0024247	BLOOD GAS ANALYSIS	55.00
108	0024247	BLOOD GAS ANALYSIS	55.00
109	0024247	BLOOD GAS ANALYSIS	55.00
110	0024247	BLOOD GAS ANALYSIS	55.00
111	0024247	BLOOD GAS ANALYSIS	55.00
112	0024247	BLOOD GAS ANALYSIS	55.00
113	0024247	BLOOD GAS ANALYSIS	55.00
114	0024247	BLOOD GAS ANALYSIS	55.00
115	0024247	BLOOD GAS ANALYSIS	55.00
116	0024247	BLOOD GAS ANALYSIS	55.00
117	0024247	BLOOD GAS ANALYSIS	55.00
118	0024247	BLOOD GAS ANALYSIS	55.00
119	0024247	BLOOD GAS ANALYSIS	55.00
120	0024247	BLOOD GAS ANALYSIS	55.00
121	0024247	BLOOD GAS ANALYSIS	55.00
122	0024247	BLOOD GAS ANALYSIS	55.00
123	0024247	BLOOD GAS ANALYSIS	55.00
124	0024247	BLOOD GAS ANALYSIS	55.00
125	0024247	BLOOD GAS ANALYSIS	55.00
126	0024410	MINOR RESP. THERAPY	73.00
127	0024410	MINOR RESP. THERAPY	68.00
128	0024420	MAJOR RESP. THERAPY	145.00
129	0024420	MAJOR RESP. THERAPY	145.00
130	0024420	MAJOR RESP. THERAPY	145.00
131	0024420	MAJOR RESP. THERAPY	145.00
132	0024420	MAJOR RESP. THERAPY	145.00
133	0024420	MAJOR RESP. THERAPY	145.00
134	0024420	MAJOR RESP. THERAPY	145.00
135	0024420	MAJOR RESP. THERAPY	145.00
136	0024420	MAJOR RESP. THERAPY	145.00
137	0024420	MAJOR RESP. THERAPY	145.00
138	0024420	MAJOR RESP. THERAPY	145.00
139	0024420	MAJOR RESP. THERAPY	145.00
140	0024430	INTENSIVE RESP. THER	272.00
141	0025040	UNIT DOSE PATIENT SU	11.95
142	0025101	ACETAMINOPHEN W/COD.	8.05
143	0025101	ACETAMINOPHEN W/COD.	8.05
144	0025101	ACETAMINOPHEN W/COD.	8.05
145	0025101	ACETAMINOPHEN W/COD.	8.05
146	0025101	ACETAMINOPHEN W/COD.	8.05
147	0025101	ACETAMINOPHEN W/COD.	8.05
148	0025101	ACETAMINOPHEN W/COD.	8.05
149	0025101	ACETAMINOPHEN W/COD.	8.05
150	0025101	ACETAMINOPHEN W/COD.	8.05
151	0025109	DIAZEPAM 2MG TAB.	8.10
152	0025109	DIAZEPAM 2MG TAB.	8.10
153	0025109	DIAZEPAM 2MG TAB.	8.10

000103

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

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IDENT=03695301

OBS	CODE	DESCRP	CHARGES
154	0025109	DIAZEPAM 2MG TAB.	8.10
155	0025109	DIAZEPAM 2MG TAB.	8.10
156	0025109	DIAZEPAM 2MG TAB.	8.10
157	0025109	DIAZEPAM 2MG TAB.	8.10
158	0025109	DIAZEPAM 2MG TAB.	8.10
159	0025109	DIAZEPAM 2MG TAB.	8.10
160	0025109	DIAZEPAM 2MG TAB.	8.10
161	0025112	DIAZEPAM 10MG INJ.	17.70
162	0025112	DIAZEPAM 10MG INJ.	17.70
163	0025122	MEPERIDINE 50MG INJ.	16.35
164	0025122	MEPERIDINE 50MG INJ.	16.35
165	0025122	MEPERIDINE 50MG INJ.	16.35
166	0025122	MEPERIDINE 50MG INJ.	16.35
167	0025122	MEPERIDINE 50MG INJ.	16.35
168	0025122	MEPERIDINE 50MG INJ.	16.35
169	0025122	MEPERIDINE 50MG INJ.	16.35
170	0025122	MEPERIDINE 50MG INJ.	16.35
171	0025122	MEPERIDINE 50MG INJ.	16.35
172	0025123	MEPERIDINE 75MG INJ.	16.38
173	0025123	MEPERIDINE 75MG INJ.	16.38
174	0025123	MEPERIDINE 75MG INJ.	16.38
175	0025123	MEPERIDINE 75MG INJ.	16.38
176	0025123	MEPERIDINE 75MG INJ.	16.38
177	0025123	MEPERIDINE 75MG INJ.	16.38
178	0025123	MEPERIDINE 75MG INJ.	16.38
179	0025144	ACETAMINOPHEN W/COD	8.25
180	0025144	ACETAMINOPHEN W/COD	8.25
181	0025163	FLURAZEPAM 15MG CAPS	8.14
182	0025163	FLURAZEPAM 15MG CAPS	8.14
183	0025178	ACETAMINOPHEN W/COD	8.21
184	0025178	ACETAMINOPHEN W/COD	8.21
185	0025178	ACETAMINOPHEN W/COD	8.21
186	0025301	0-.25 UNIT DOSE SOLI	2.70
187	0025301	0-.25 UNIT DOSE SOLI	2.70
188	0025301	0-.25 UNIT DOSE SOLI	16.20
189	0025301	0-.25 UNIT DOSE SOLI	2.70
190	0025301	0-.25 UNIT DOSE SOLI	1.35
191	0025301	0-.25 UNIT DOSE SOLI	4.05
192	0025301	0-.25 UNIT DOSE SOLI	1.35
193	0025301	0-.25 UNIT DOSE SOLI	1.35
194	0025301	0-.25 UNIT DOSE SOLI	1.35
195	0025301	0-.25 UNIT DOSE SOLI	1.35
196	0025301	0-.25 UNIT DOSE SOLI	1.35
197	0025301	0-.25 UNIT DOSE SOLI	16.20
198	0025302	26-.50 UNIT DOSE SO	49.60
199	0025302	26-.50 UNIT DOSE SO	12.80
200	0025302	26-.50 UNIT DOSE SO	64.00
201	0025332	ATROPINE INJ. 0-600M	7.17
202	0025332	ATROPINE INJ. 0-600M	7.60
203	0025372	PROMETHAZINE INJ. 0-	7.60
204	0025372	ADULT UD LIQ 0-.50	9.00

000104

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
 DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
 JULY 1984 - DECEMBER 1984

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IDENT=03695301

OBS	CODE	DESCRP	CHARGES
205	0025372	ADULT UD LIQ 0-.50	12.00
206	0025373	ADULT UD LIQ .51-1.0	108.00
207	0025373	ADULT UD LIQ .51-1.0	108.00
208	0025392	ADULT INJ 0-1.00	24.00
209	0025392	ADULT INJ 0-1.00	16.00
210	0025392	ADULT INJ 0-1.00	8.00
211	0025396	ADULT INJ MISC	12.00
212	0025701	PRIMARY SOLN-PLAIN	46.00
213	0025701	PRIMARY SOLN-PLAIN	23.00
214	0025701	PRIMARY SOLN-PLAIN	138.00
215	0025701	PRIMARY SOLN-PLAIN	23.00
216	0025701	PRIMARY SOLN-PLAIN	23.00
217	0025701	PRIMARY SOLN-PLAIN	46.00
218	0025701	PRIMARY SOLN-PLAIN	46.00
219	0025701	PRIMARY SOLN-PLAIN	23.00
220	0025702	PRIMARY SOLN-W/K+	48.40
221	0025702	PRIMARY SOLN-W/K+	48.40
222	0025702	PRIMARY SOLN-W/K+	72.60
223	0025702	PRIMARY SOLN-W/K+	72.60
224	0025702	PRIMARY SOLN-W/K+	72.60
225	0025702	PRIMARY SOLN-W/K+	24.20
226	0025702	PRIMARY SOLN-W/K+	48.40
227	0025702	PRIMARY SOLN-W/K+	72.60
228	0025702	PRIMARY SOLN-W/K+	48.40
229	0025702	PRIMARY SOLN-W/K+	24.20
230	0025702	PRIMARY SOLN-W/K+	48.40
231	0025702	PRIMARY SOLN-W/K+	24.20
232	0025728	CEFOXITIN 0.6-1.5GM	170.04
233	0025728	CEFOXITIN 0.6-1.5GM	170.04
234	0025728	CEFOXITIN 0.6-1.5GM	170.04
235	0025728	CEFOXITIN 0.6-1.5GM	85.02
236	0025728	CEFOXITIN 0.6-1.5GM	170.04
237	0025728	CEFOXITIN 0.6-1.5GM	170.04
238	0025853	IV ADMIXTURES	28.60
239	0025853	IV ADMIXTURES	29.00
240	0025853	IV ADMIXTURES	29.00
241	0025890	NUTRITION SOLUTION	156.00
242	0026110	GAIT TRAINING	53.00
243	0026110	GAIT TRAINING	38.00
244	0026110	GAIT TRAINING	38.00
245	0026110	GAIT TRAINING	38.00
246	0026110	GAIT TRAINING	53.00
247	0026110	GAIT TRAINING	38.00
248	0026112	PHYS THER PROCEDURES	38.00
249	0026112	PHYS THER PROCEDURES	38.00
250	0026112	PHYS THER PROCEDURES	38.00
251	0026112	PHYS THER PROCEDURES	38.00
252	0026112	PHYS THER PROCEDURES	38.00
253	0026113	PHYS THER PROCEDURES	53.00
254	0026113	PHYS THER PROCEDURES	48.00
255	0028150	EMERGENCY DEPT. VISI	55.00

000105

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

16:03 TUESDAY, AUGUST 20, 1985

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IDENT=03695301

OBS	CODE	DESCRP	CHARGES
256	0030016	BLOOD BANK ADMIN. PE	100.00
257	0030016	BLOOD BANK ADMIN. PE	50.00
258	0030016	BLOOD BANK ADMIN. PE	100.00
259	0030016	BLOOD BANK ADMIN. PE	45.00
260	0030113	PRE-TRANSFUSION TEST	65.00
261	0030318	COMPATIBILITY TESTIN	51.00
262	0030318	COMPATIBILITY TESTIN	90.00
263	0030498	TYPE AND SCREEN	65.00
264	0030498	TYPE AND SCREEN	45.00
265	0030503	PACKED RED BLOOD CEL	160.00
266	0030503	PACKED RED BLOOD CEL	80.00
267	0030503	PACKED RED BLOOD CEL	160.00
268	0030503	PACKED RED BLOOD CEL	72.00
269	0030560	COMPATIB. TEST-STAT	112.00
270	0030560	COMPATIB. TEST-STAT	112.00
271	0030906	PRE-TRANSFUSION TEST	55.00
272	0034510	STANDARD EKG-OVER 6	43.00
273	0034510	STANDARD EKG-OVER 6	43.00
274	0034510	STANDARD EKG-OVER 6	39.00
275	0041461	16SW DSC PRIVATE	455.00
276	0041472	T6NE DSC SEMI-PRIVAT	445.00
277	0041472	T6NE DSC SEMI-PRIVAT	445.00
278	0041472	T6NE DSC SEMI-PRIVAT	445.00
279	0041472	T6NE DSC SEMI-PRIVAT	445.00
280	0041472	T6NE DSC SEMI-PRIVAT	445.00
281	0041472	T6NE DSC SEMI-PRIVAT	445.00
282	0041472	T6NE DSC SEMI-PRIVAT	445.00
283	0041472	T6NE DSC SEMI-PRIVAT	445.00
284	0041472	T6NE DSC SEMI-PRIVAT	445.00
285	0041472	T6NE DSC SEMI-PRIVAT	445.00
286	0041472	T6NE DSC SEMI-PRIVAT	445.00
287	0041472	T6NE DSC SEMI-PRIVAT	445.00
288	0041472	T6NE DSC SEMI-PRIVAT	445.00
289	0041472	T6NE DSC SEMI-PRIVAT	445.00
290	0041472	T6NE DSC SEMI-PRIVAT	445.00
291	0041472	T6NE DSC SEMI-PRIVAT	445.00
292	0041472	T6NE DSC SEMI-PRIVAT	445.00
293	0041472	T6NE DSC SEMI-PRIVAT	445.00
294	0041472	T6NE DSC SEMI-PRIVAT	445.00
295	0041472	T6NE DSC SEMI-PRIVAT	445.00
296	0041472	T6NE DSC SEMI-PRIVAT	445.00
297	0041472	T6NE DSC SEMI-PRIVAT	445.00
298	0041472	T6NE DSC SEMI-PRIVAT	415.00
299	0041472	T6NE DSC SEMI-PRIVAT	415.00
300	0041472	T6NE DSC SEMI-PRIVAT	445.00
301	0041472	T6NE DSC SEMI-PRIVAT	445.00
302	0041472	T6NE DSC SEMI-PRIVAT	445.00
303	0041472	T6NE DSC SEMI-PRIVAT	445.00
304	0041472	T6NE DSC SEMI-PRIVAT	445.00
305	0041472	T6NE DSC SEMI-PRIVAT	415.00
306	0041472	T6NE DSC SEMI-PRIVAT	415.00

0001000

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

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OBS	CODE	DESCRIP	CHARGES
307	0041472	T6NE DSC SEMI-PRIVAT	415.00
308	0041472	T6NE DSC SEMI-PRIVAT	415.00
309	0041472	T6NE DSC SEMI-PRIVAT	415.00
310	0041472	T6NE DSC SEMI-PRIVAT	415.00
311	0041472	T6NE DSC SEMI-PRIVAT	445.00
312	0041472	T6NE DSC SEMI-PRIVAT	445.00
313	0041472	T6NE DSC SEMI-PRIVAT	415.00
314	0041472	T6NE DSC SEMI-PRIVAT	415.00
315	0041472	T6NE DSC SEMI-PRIVAT	415.00
316	0041472	T6NE DSC SEMI-PRIVAT	415.00
317	0041472	T6NE DSC SEMI-PRIVAT	415.00
318	0041472	T6NE DSC SEMI-PRIVAT	415.00
319	0041472	T6NE DSC SEMI-PRIVAT	415.00
320	0041472	T6NE DSC SEMI-PRIVAT	415.00
321	0041472	T6NE DSC SEMI-PRIVAT	415.00
322	0041472	T6NE DSC SEMI-PRIVAT	415.00
323	0041472	T6NE DSC SEMI-PRIVAT	415.00
324	0041472	T6NE DSC SEMI-PRIVAT	415.00
325	0041472	T6NE DSC SEMI-PRIVAT	415.00
326	0041472	T6NE DSC SEMI-PRIVAT	415.00
327	0041472	T6NE DSC SEMI-PRIVAT	415.00
328	0041472	T6NE DSC SEMI-PRIVAT	415.00
329	0041472	T6NE DSC SEMI-PRIVAT	415.00
330	0041472	T6NE DSC SEMI-PRIVAT	415.00
331	0041472	T6NE DSC SEMI-PRIVAT	415.00
332	0041472	T6NE DSC SEMI-PRIVAT	415.00
333	0041472	T6NE DSC SEMI-PRIVAT	415.00
334	0041472	T6NE DSC SEMI-PRIVAT	415.00
335	0041472	T6NE DSC SEMI-PRIVAT	415.00
336	0041472	T6NE DSC SEMI-PRIVAT	415.00
337	0041472	T6NE DSC SEMI-PRIVAT	415.00
338	0041472	T6NE DSC SEMI-PRIVAT	415.00
339	0041472	T6NE DSC SEMI-PRIVAT	415.00
340	0041472	T6NE DSC SEMI-PRIVAT	415.00
341	0041472	T6NE DSC SEMI-PRIVAT	415.00
342	0041472	T6NE DSC SEMI-PRIVAT	415.00
343	0041472	T6NE DSC SEMI-PRIVAT	415.00
344	0041472	T6NE DSC SEMI-PRIVAT	415.00
345	0041472	T6NE DSC SEMI-PRIVAT	415.00
346	0041472	T6NE DSC SEMI-PRIVAT	415.00
347	0041472	T6NE DSC SEMI-PRIVAT	415.00
348	0041472	T6NE DSC SEMI-PRIVAT	415.00
349	0041472	T6NE DSC SEMI-PRIVAT	415.00
350	0041472	T6NE DSC SEMI-PRIVAT	415.00
351	0041472	T6NE DSC SEMI-PRIVAT	415.00
352	0041472	T6NE DSC SEMI-PRIVAT	415.00
353	0041472	T6NE DSC SEMI-PRIVAT	415.00
354	0041472	T6NE DSC SEMI-PRIVAT	415.00
355	0041472	T6NE DSC SEMI-PRIVAT	415.00
356	0041472	T6NE DSC SEMI-PRIVAT	415.00
357	0041472	T6NE DSC SEMI-PRIVAT	415.00

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THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
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OBS	CODE	DESCR	CHARGES
358	0043272	ELECTROLYTES	27.00
359	0043272	ELECTROLYTES	27.00
360	0043272	ELECTROLYTES	27.00
361	0043272	ELECTROLYTES	27.00
362	0043272	ELECTROLYTES	25.00
363	0043272	ELECTROLYTES	25.00
364	0043272	ELECTROLYTES	27.00
365	0043272	ELECTROLYTES	25.00
366	0043272	ELECTROLYTES	25.00
367	0043272	ELECTROLYTES	25.00
368	0043272	ELECTROLYTES	25.00
369	0043272	ELECTROLYTES	25.00
370	0043272	ELECTROLYTES	25.00
371	0043304	ALKALINE PHOSPHATASE	18.00
372	0043305	BILIRUBIN, TOTAL	11.00
373	0043307	BLOOD UREA NITROGEN	15.00
374	0043307	BLOOD UREA NITROGEN	15.00
375	0043307	BLOOD UREA NITROGEN	15.00
376	0043307	BLOOD UREA NITROGEN	15.00
377	0043307	BLOOD UREA NITROGEN	15.00
378	0043307	BLOOD UREA NITROGEN	15.00
379	0043307	BLOOD UREA NITROGEN	15.00
380	0043307	BLOOD UREA NITROGEN	15.00
381	0043307	BLOOD UREA NITROGEN	15.00
382	0043307	BLOOD UREA NITROGEN	15.00
383	0043307	BLOOD UREA NITROGEN	15.00
384	0043307	BLOOD UREA NITROGEN	15.00
385	0043307	BLOOD UREA NITROGEN	14.00
386	0043307	BLOOD UREA NITROGEN	14.00
387	0043307	BLOOD UREA NITROGEN	15.00
388	0043307	BLOOD UREA NITROGEN	14.00
389	0043307	BLOOD UREA NITROGEN	14.00
390	0043307	BLOOD UREA NITROGEN	14.00
391	0043307	BLOOD UREA NITROGEN	14.00
392	0043307	BLOOD UREA NITROGEN	14.00
393	0043307	BLOOD UREA NITROGEN	14.00
394	0043310	SPINAL FLUID PROTEIN	20.50
395	0043311	SPINAL FLUID GLUCOSE	17.25
396	0043312	CHOLESTEROL	27.00
397	0043312	CHOLESTEROL	27.00
398	0043312	CHOLESTEROL	25.00
399	0043314	ALKALINE PHOSPHATASE	25.00
400	0043314	ALKALINE PHOSPHATASE	25.00
401	0043314	ALKALINE PHOSPHATASE	23.00
402	0043315	BILIRUBIN-TOTAL, SERU	17.25
403	0043315	BILIRUBIN-TOTAL, SERU	17.25
404	0043315	BILIRUBIN-TOTAL, SERU	16.00
405	0043315	BILIRUBIN-TOTAL, SERU	16.00
406	0043316	CREATINE PHOSPHOKINA	20.50
407	0043317	BLOOD UREA NITROGEN	20.50
408	0043317	BLOOD UREA NITROGEN	20.50

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OBS	CODE	DESCRP	CHARGES
409	0043317	BLOOD UREA NITROGEN	20.50
410	0043317	BLOOD UREA NITROGEN	20.50
411	0043317	BLOOD UREA NITROGEN	20.50
412	0043317	BLOOD UREA NITROGEN	20.50
413	0043317	BLOOD UREA NITROGEN	20.50
414	0043317	BLOOD UREA NITROGEN	20.50
415	0043317	BLOOD UREA NITROGEN	20.50
416	0043317	BLOOD UREA NITROGEN	20.50
417	0043317	BLOOD UREA NITROGEN	19.00
418	0043317	BLOOD UREA NITROGEN	20.50
419	0043317	BLOOD UREA NITROGEN	19.00
420	0043317	BLOOD UREA NITROGEN	19.00
421	0043317	BLOOD UREA NITROGEN	19.00
422	0043317	BLOOD UREA NITROGEN	19.00
423	0043322	CPK ISOENZYMES	75.00
424	0043322	CPK ISOENZYMES	75.00
425	0043322	CPK ISOENZYMES	75.00
426	0043362	MAGNESIUM	23.75
427	0043362	MAGNESIUM	23.75
428	0043362	MAGNESIUM	23.75
429	0043362	MAGNESIUM	23.75
430	0043362	MAGNESIUM	23.75
431	0043362	MAGNESIUM	23.75
432	0043362	MAGNESIUM	23.75
433	0043362	MAGNESIUM	23.75
434	0043362	MAGNESIUM	23.75
435	0043362	MAGNESIUM	23.75
436	0043362	MAGNESIUM	23.75
437	0043362	MAGNESIUM	23.75
438	0043362	MAGNESIUM	23.75
439	0043362	MAGNESIUM	23.75
440	0043362	MAGNESIUM	23.75
441	0043362	MAGNESIUM	23.75
442	0043362	MAGNESIUM	22.00
443	0043362	MAGNESIUM	22.00
444	0043362	MAGNESIUM	23.75
445	0043362	MAGNESIUM	22.00
446	0043362	MAGNESIUM	22.00
447	0043372	ALBUMIN	12.00
448	0043372	ALBUMIN	12.00
449	0043372	ALBUMIN	11.00
450	0043377	CALCIUM, SERUM	15.00
451	0043377	CALCIUM, SERUM	15.00
452	0043377	CALCIUM, SERUM	15.00
453	0043377	CALCIUM, SERUM	15.00
454	0043377	CALCIUM, SERUM	15.00
455	0043377	CALCIUM, SERUM	15.00
456	0043377	CALCIUM, SERUM	15.00
457	0043377	CALCIUM, SERUM	15.00
458	0043377	CALCIUM, SERUM	15.00
459	0043377	CALCIUM, SERUM	15.00

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OBS	CODE	DESCR	CHARGES
460	0043377	CALCIUM, SERUM	15.00
461	0043377	CALCIUM, SERUM	15.00
462	0043377	CALCIUM, SERUM	15.00
463	0043377	CALCIUM, SERUM	15.00
464	0043377	CALCIUM, SERUM	15.00
465	0043377	CALCIUM, SERUM	14.00
466	0043385	CREATININE, BLOOD	12.00
467	0043385	CREATININE, BLOOD	12.00
468	0043385	CREATININE, BLOOD	12.00
469	0043385	CREATININE, BLOOD	12.00
470	0043385	CREATININE, BLOOD	12.00
471	0043385	CREATININE, BLOOD	12.00
472	0043385	CREATININE, BLOOD	12.00
473	0043385	CREATININE, BLOOD	12.00
474	0043385	CREATININE, BLOOD	12.00
475	0043385	CREATININE, BLOOD	12.00
476	0043385	CREATININE, BLOOD	12.00
477	0043385	CREATININE, BLOOD	12.00
478	0043385	CREATININE, BLOOD	11.00
479	0043385	CREATININE, BLOOD	11.00
480	0043385	CREATININE, BLOOD	12.00
481	0043385	CREATININE, BLOOD	11.00
482	0043385	CREATININE, BLOOD	11.00
483	0043385	CREATININE, BLOOD	11.00
484	0043385	CREATININE, BLOOD	11.00
485	0043385	CREATININE, BLOOD	11.00
486	0043385	CREATININE, BLOOD	11.00
487	0043394	INORGANIC PHOSPHATE	14.00
488	0043394	INORGANIC PHOSPHATE	14.00
489	0043394	INORGANIC PHOSPHATE	14.00
490	0043394	INORGANIC PHOSPHATE	14.00
491	0043394	INORGANIC PHOSPHATE	14.00
492	0043394	INORGANIC PHOSPHATE	14.00
493	0043394	INORGANIC PHOSPHATE	14.00
494	0043394	INORGANIC PHOSPHATE	14.00
495	0043394	INORGANIC PHOSPHATE	14.00
496	0043394	INORGANIC PHOSPHATE	14.00
497	0043394	INORGANIC PHOSPHATE	14.00
498	0043394	INORGANIC PHOSPHATE	14.00
499	0043394	INORGANIC PHOSPHATE	14.00
500	0043394	INORGANIC PHOSPHATE	14.00
501	0043394	INORGANIC PHOSPHATE	14.00
502	0043394	INORGANIC PHOSPHATE	14.00
503	0043394	INORGANIC PHOSPHATE	14.00
504	0043394	AMMONIA	13.00
505	0043402	GLUCOSE FASTING	68.00
506	0043404	GLUCOSE FASTING	12.00
507	0043404	GLUCOSE FASTING	12.00
508	0043404	GLUCOSE FASTING	12.00
509	0043404	GLUCOSE FASTING	12.00
510	0043404	GLUCOSE FASTING	12.00

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OBS	CODE	DESCR	CHARGES
511	0043404	GLUCOSE FASTING	12.00
512	0043404	GLUCOSE FASTING	12.00
513	0043404	GLUCOSE FASTING	12.00
514	0043404	GLUCOSE FASTING	12.00
515	0043404	GLUCOSE FASTING	12.00
516	0043404	GLUCOSE FASTING	12.00
517	0043404	GLUCOSE FASTING	12.00
518	0043404	GLUCOSE FASTING	11.00
519	0043404	GLUCOSE FASTING	11.00
520	0043404	GLUCOSE FASTING	11.00
521	0043404	GLUCOSE FASTING	11.00
522	0043405	GLUCOSE, NONFASTING	12.00
523	0043405	GLUCOSE, NONFASTING	12.00
524	0043405	GLUCOSE, NONFASTING	12.00
525	0043405	GLUCOSE, NONFASTING	12.00
526	0043405	GLUCOSE, NONFASTING	12.00
527	0043405	GLUCOSE, NONFASTING	12.00
528	0043405	GLUCOSE, NONFASTING	11.00
529	0043422	LACTIC DEHYDROGENASE	19.50
530	0043422	LACTIC DEHYDROGENASE	18.00
531	0043437	SGPT	18.00
532	0043441	TOTAL PROTEIN	15.00
533	0043441	TOTAL PROTEIN	15.00
534	0043441	TOTAL PROTEIN	14.00
535	0043442	SGOT-TRANSAMINASE-ST	25.00
536	0043442	SGOT-TRANSAMINASE-ST	25.00
537	0043442	SGOT-TRANSAMINASE-ST	23.00
538	0043442	SGOT-TRANSAMINASE-ST	23.00
539	0043449	CREATININE-URINE/FLU	11.00
540	0043450	CHEM 17 SCREEN	47.50
541	0043463	AMYLASE SERUM STAT	25.00
542	0043463	AMYLASE SERUM STAT	23.00
543	0043477	CALCIUM-SERUM, STAT	20.50
544	0043477	CALCIUM-SERUM, STAT	20.50
545	0043477	CALCIUM-SERUM, STAT	20.50
546	0043477	CALCIUM-SERUM, STAT	20.50
547	0043477	CALCIUM-SERUM, STAT	20.50
548	0043477	CALCIUM-SERUM, STAT	20.50
549	0043477	CALCIUM-SERUM, STAT	20.50
550	0043477	CALCIUM-SERUM, STAT	20.50
551	0043477	CALCIUM-SERUM, STAT	20.50
552	0043477	CALCIUM-SERUM, STAT	20.50
553	0043477	CALCIUM-SERUM, STAT	19.00
554	0043477	CALCIUM-SERUM, STAT	19.00
555	0043485	CREATININE-SERUM-STA	19.00
556	0043485	CREATININE-SERUM-STA	17.25
557	0043485	CREATININE-SERUM-STA	17.25
558	0043485	CREATININE-SERUM-STA	17.25
559	0043485	CREATININE-SERUM-STA	17.25
560	0043485	CREATININE-SERUM-STA	17.25
561	0043485	CREATININE-SERUM-STA	17.25

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OBS	CODE	DESCRP	CHARGES
562	0043485	CREATININE-SERUM-STA	17.25
563	0043485	CREATININE-SERUM-STA	17.25
564	0043485	CREATININE-SERUM-STA	17.25
565	0043485	CREATININE-SERUM-STA	17.25
566	0043485	CREATININE-SERUM-STA	17.25
567	0043485	CREATININE-SERUM-STA	17.25
568	0043485	CREATININE-SERUM-STA	17.25
569	0043485	CREATININE-SERUM-STA	16.00
570	0043485	CREATININE-SERUM-STA	16.00
571	0043485	CREATININE-SERUM-STA	16.00
572	0043504	GLUCOSE FASTING-FBS	17.25
573	0043504	GLUCOSE FASTING-FBS	17.25
574	0043504	GLUCOSE FASTING-FBS	17.25
575	0043505	GLUCOSE NONFASTING-N	17.25
576	0043505	GLUCOSE NONFASTING-N	17.25
577	0043505	GLUCOSE NONFASTING-N	17.25
578	0043505	GLUCOSE NONFASTING-N	17.25
579	0043505	GLUCOSE NONFASTING-N	16.00
580	0043505	GLUCOSE NONFASTING-N	17.25
581	0043505	GLUCOSE NONFASTING-N	16.00
582	0043516	CREATINE PHOSPHORINA	26.00
583	0043516	CREATINE PHOSPHORINA	26.00
584	0043516	CREATINE PHOSPHORINA	24.00
585	0043522	LDH-LACTIC DEHYDROCE	25.00
586	0043522	LDH-LACTIC DEHYDROCE	25.00
587	0043522	LDH-LACTIC DEHYDROCE	23.00
588	0043522	LDH-LACTIC DEHYDROCE	23.00
589	0043537	SGPT TRANSAMINASE ST	25.00
590	0043537	SGPT TRANSAMINASE ST	25.00
591	0043537	SGPT TRANSAMINASE ST	23.00
592	0043537	SGPT TRANSAMINASE ST	23.00
593	0043562	MAGNESIUM SERUM STAT	28.00
594	0043562	MAGNESIUM SERUM STAT	28.00
595	0043562	MAGNESIUM SERUM STAT	28.00
596	0043562	MAGNESIUM SERUM STAT	28.00
597	0043562	MAGNESIUM SERUM STAT	28.00
598	0043562	MAGNESIUM SERUM STAT	28.00
599	0043562	MAGNESIUM SERUM STAT	28.00
600	0043562	MAGNESIUM SERUM STAT	28.00
601	0043562	MAGNESIUM SERUM STAT	28.00
602	0043562	MAGNESIUM SERUM STAT	28.00
603	0043562	MAGNESIUM SERUM STAT	28.00
604	0043562	MAGNESIUM SERUM STAT	26.00
605	0043562	MAGNESIUM SERUM STAT	26.00
606	0043598	KIDNEY PROFILE	29.25
607	0043598	KIDNEY PROFILE	29.25
608	0043598	KIDNEY PROFILE	29.25
609	0043598	KIDNEY PROFILE	29.25
610	0043598	KIDNEY PROFILE	29.25
611	0043598	KIDNEY PROFILE	27.00
612	0043598	KIDNEY PROFILE	27.00

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OBS	CODE	DESCRIP	CHARGES
613	0043598	KIDNEY PROFILE	29.25
614	0043599	LIVER PROFILE	31.25
615	0043599	LIVER PROFILE	31.25
616	0043599	LIVER PROFILE	31.25
617	0043599	LIVER PROFILE	31.25
618	0044219	ANTI-THROMBIN III	86.00
619	0044233	CIRCULATING ANTICOAG	86.00
620	0044235	PROTHAMINE SULFATE	57.00
621	0044422	PLASMINOGEN ASSAY	156.00
622	0044495	D.I.C. SCREENING	151.00
623	0044561	FACTOR V ASSAY	80.00
624	0044562	FACTOR VII ASSAY	80.00
625	0044563	FACTOR VIII ASSAY	80.00
626	0044564	FACTOR IX ASSAY	80.00
627	0044566	FACTOR XI ASSAY	80.00
628	0044567	FACTOR XII ASSAY	80.00
629	0047207	BODY FLUIDS-CSF	73.98
630	0047207	BODY FLUIDS-CSF	73.98
631	0049708	ESOPHAGOGASTRODUDEN	506.00
632	0049709	ESOPHAGOGASTRODUDEN	106.00
633	0049709	ESOPHAGOGASTRODUDEN	508.00
634	0049895	COLONOSCOPY CPT BYD H	198.00
635	0050037	ENT CLINIC CONSULT-1	21.00
636	0052289	MICROSCOPIC PATHOLOG	116.00
637	0052290	MICROSCOPIC PATHOLOG	167.00
638	0053211	BLOOD COUNT (CBC)	12.00
639	0053211	BLOOD COUNT (CBC)	12.00
640	0053211	BLOOD COUNT (CBC)	12.00
641	0053211	BLOOD COUNT (CBC)	12.00
642	0053211	BLOOD COUNT (CBC)	12.00
643	0053211	BLOOD COUNT (CBC)	12.00
644	0053211	BLOOD COUNT (CBC)	12.00
645	0053211	BLOOD COUNT (CBC)	12.00
646	0053211	BLOOD COUNT (CBC)	12.00
647	0053211	BLOOD COUNT (CBC)	12.00
648	0053211	BLOOD COUNT (CBC)	12.00
649	0053211	BLOOD COUNT (CBC)	12.00
650	0053211	BLOOD COUNT (CBC)	12.00
651	0053211	BLOOD COUNT (CBC)	12.00
652	0053211	BLOOD COUNT (CBC)	12.00
653	0053211	BLOOD COUNT (CBC)	12.00
654	0053211	BLOOD COUNT (CBC)	12.00
655	0053211	BLOOD COUNT (CBC)	11.00
656	0053211	BLOOD COUNT (CBC)	11.00
657	0053211	BLOOD COUNT (CBC)	11.00
658	0053211	BLOOD COUNT (CBC)	11.00
659	0053211	BLOOD COUNT (CBC)	11.00
660	0053211	BLOOD COUNT (CBC)	11.00
661	0053211	BLOOD COUNT (CBC)	11.00
662	0053211	BLOOD COUNT (CBC)	11.00
663	0053215	DIFFERENTIAL	13.00

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OBS	CODE	DESCR	CHARGES
664	0053215	DIFFERENTIAL	13.00
665	0053215	DIFFERENTIAL	13.00
666	0053215	DIFFERENTIAL	13.00
667	0053215	DIFFERENTIAL	13.00
668	0053215	DIFFERENTIAL	13.00
669	0053215	DIFFERENTIAL	13.00
670	0053215	DIFFERENTIAL	13.00
671	0053215	DIFFERENTIAL	13.00
672	0053215	DIFFERENTIAL	13.00
673	0053215	DIFFERENTIAL	13.00
674	0053215	DIFFERENTIAL	13.00
675	0053215	DIFFERENTIAL	13.00
676	0053215	DIFFERENTIAL	13.00
677	0053215	DIFFERENTIAL	13.00
678	0053215	DIFFERENTIAL	13.00
679	0053215	DIFFERENTIAL	13.00
680	0053215	DIFFERENTIAL	12.00
681	0053215	DIFFERENTIAL	12.00
682	0053215	DIFFERENTIAL	12.00
683	0053215	DIFFERENTIAL	12.00
684	0053215	DIFFERENTIAL	12.00
685	0053215	DIFFERENTIAL	12.00
686	0053215	DIFFERENTIAL	12.00
687	0053215	DIFFERENTIAL	12.00
688	0053215	DIFFERENTIAL	12.00
689	0053220	DIFFERENTIAL	11.00
690	0053302	APT	13.00
691	0053302	APT	13.00
692	0053302	APT	12.00
693	0053302	APT	12.00
694	0053311	BLOOD COUNT (CBC) -	20.00
695	0053311	BLOOD COUNT (CBC) -	20.00
696	0053311	BLOOD COUNT (CBC) -	20.00
697	0053311	BLOOD COUNT (CBC) -	20.00
698	0053311	BLOOD COUNT (CBC) -	20.00
699	0053311	BLOOD COUNT (CBC) -	20.00
700	0053311	BLOOD COUNT (CBC) -	20.00
701	0053311	BLOOD COUNT (CBC) -	20.00
702	0053311	BLOOD COUNT (CBC) -	20.00
703	0053311	BLOOD COUNT (CBC) -	18.00
704	0053311	BLOOD COUNT (CBC) -	20.00
705	0053311	BLOOD COUNT (CBC) -	18.00
706	0053311	BLOOD COUNT (CBC) -	20.00
707	0053311	BLOOD COUNT (CBC) -	18.00
708	0053311	BLOOD COUNT (CBC) -	18.00
709	0053311	BLOOD COUNT (CBC) -	18.00
710	0053311	BLOOD COUNT (CBC) -	18.00
711	0053311	BLOOD COUNT (CBC) -	18.00
712	0053315	DIFFERENTIAL - STAT	23.00
713	0053315	DIFFERENTIAL - STAT	23.00
714	0053315	DIFFERENTIAL - STAT	23.00

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OBS	CODE	DESCR	CHARGES
715	0053315	DIFFERENTIAL - STAT	23.00
716	0053315	DIFFERENTIAL - STAT	23.00
717	0053315	DIFFERENTIAL - STAT	23.00
718	0053315	DIFFERENTIAL - STAT	23.00
719	0053315	DIFFERENTIAL - STAT	23.00
720	0053315	DIFFERENTIAL - STAT	23.00
721	0053315	DIFFERENTIAL - STAT	23.00
722	0053315	DIFFERENTIAL - STAT	23.00
723	0053315	DIFFERENTIAL - STAT	21.00
724	0053315	DIFFERENTIAL - STAT	23.00
725	0053315	DIFFERENTIAL - STAT	21.00
726	0053315	DIFFERENTIAL - STAT	21.00
727	0053320	DIFFERENTIAL - STAT	21.00
728	0053320	URINALYSIS - STAT	18.00
729	0053402	APT-STAT	20.00
730	0053402	APT-STAT	18.00
731	0053418	PT	13.00
732	0053418	PT	13.00
733	0053418	PT	12.00
734	0053418	PT	12.00
735	0053449	PLATELET COUNT	10.50
736	0053449	PLATELET COUNT	10.50
737	0053449	PLATELET COUNT	10.50
738	0053449	PLATELET COUNT	10.50
739	0053449	PLATELET COUNT	10.50
740	0053449	PLATELET COUNT	10.50
741	0053449	PLATELET COUNT	10.50
742	0053449	PLATELET COUNT	10.50
743	0053449	PLATELET COUNT	10.50
744	0053449	PLATELET COUNT	10.50
745	0053449	PLATELET COUNT	10.50
746	0053449	PLATELET COUNT	10.50
747	0053449	PLATELET COUNT	10.50
748	0053449	PLATELET COUNT	10.50
749	0053449	PLATELET COUNT	10.50
750	0053449	PLATELET COUNT	10.50
751	0053449	PLATELET COUNT	10.50
752	0053449	PLATELET COUNT	10.00
753	0053449	PLATELET COUNT	10.00
754	0053449	PLATELET COUNT	10.00
755	0053449	PLATELET COUNT	10.00
756	0053449	PLATELET COUNT	10.00
757	0053450	RETICULOCYTE COUNT	12.50
758	0053450	RETICULOCYTE COUNT	12.00
759	0053450	RETICULOCYTE COUNT	12.00
760	0053450	RETICULOCYTE COUNT	12.00
761	0053460	SPINAL FLUID	28.00
762	0053460	SPINAL FLUID	28.00
763	0053469	PLATELET COUNT - STA	18.50
764	0053469	PLATELET COUNT - STA	18.50
765	0053469	PLATELET COUNT - STA	18.50

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
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OBS	CODE	DESCRP	CHARGES
766	0053469	PLATELET COUNT - STA	18.50
767	0053469	PLATELET COUNT - STA	18.50
768	0053469	PLATELET COUNT - STA	18.50
769	0053469	PLATELET COUNT - STA	18.50
770	0053469	PLATELET COUNT - STA	18.50
771	0053469	PLATELET COUNT - STA	18.50
772	0053469	PLATELET COUNT - STA	17.00
773	0053469	PLATELET COUNT - STA	17.00
774	0053469	PLATELET COUNT - STA	17.00
775	0053518	PT-STAT	20.00
776	0053518	PT-STAT	18.00
777	0053560	FDP - STAT	33.50
778	0058295	FUNGUS EXAM	41.00
779	0058328	BLOOD CULTURE	45.00
780	0058328	BLOOD CULTURE	45.00
781	0058328	BLOOD CULTURE	45.00
782	0058328	BLOOD CULTURE	40.00
783	0058328	BLOOD CULTURE	40.00
784	0058332	AFB	60.00
785	0058332	AFB	60.00
786	0058450	SERUM ANTIMICROBIAL	41.00
787	0058462	URINE CULTURE	22.00
788	0058462	URINE CULTURE	22.00
789	0058462	URINE CULTURE	22.00
790	0058462	URINE CULTURE	20.00
791	0058462	URINE CULTURE	20.00
792	0058464	RESP. CULTURE-UPPER	39.00
793	0058464	RESP. CULTURE-UPPER	37.00
794	0058464	RESP. CULTURE-UPPER	39.00
795	0058464	RESP. CULTURE-UPPER	37.00
796	0058466	NOSE/THROAT CULTURE-	23.00
797	0058468	IDENT AND SUCS TEST	52.00
798	0058468	IDENT AND SUCS TEST	52.00
799	0058468	IDENT AND SUCS TEST	52.00
800	0058468	IDENT AND SUCS TEST	52.00
801	0058468	IDENT AND SUCS TEST	52.00
802	0058468	IDENT AND SUCS TEST	52.00
803	0058468	IDENT AND SUCS TEST	52.00
804	0058468	IDENT AND SUCS TEST	52.00
805	0058468	IDENT AND SUCS TEST	52.00
806	0058468	IDENT AND SUCS TEST	52.00
807	0058468	IDENT AND SUCS TEST	52.00
808	0058468	IDENT AND SUCS TEST	52.00
809	0058468	IDENT AND SUCS TEST	52.00
810	0058468	IDENT AND SUCS TEST	52.00
811	0058468	IDENT AND SUCS TEST	52.00
812	0058468	IDENT AND SUCS TEST	52.00
813	0058468	IDENT AND SUCS TEST	48.00
814	0058468	IDENT AND SUCS TEST	52.00
815	0058468	IDENT AND SUCS TEST	48.00
816	0058473	BODY FLUID CULTURE	38.00

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OBS	CODE	DESCRP	CHARGES
817	0058473	BODY FLUID CULTURE	38.00
818	0063354	FTI	50.00
819	0063376	TSH	45.00
820	0066221	VDRL SCREEN	13.00
821	0069271	TRUE VITAMIN B12	50.00
822	0069321	CARCINOEMBRYONIC ANT	105.00
823	0079027	00220 INTRAORAL-STING	10.00
824	0079038	00330 PANDRAMIC (MAX	45.00
825	7700027	VANCOMYCIN 0-500MG	53.40
826	7700027	VANCOMYCIN 0-500MG	106.80
827	7700027	VANCOMYCIN 0-500MG	160.20
828	7700069	PENICILLIN K+ (ALL D	111.72
829	7700069	PENICILLIN K+ (ALL D	148.96
830	7700115	CEFOXITIN 0.6-1.5GM	184.80
831	7700115	CEFOXITIN 0.6-1.5GM	46.20
832	7700115	CEFOXITIN 0.6-1.5GM	184.80
833	7700115	CEFOXITIN 0.6-1.5GM	138.60
834	7700115	CEFOXITIN 0.6-1.5GM	138.60
835	7700115	CEFOXITIN 0.6-1.5GM	46.20
836	7700115	CEFOXITIN 0.6-1.5GM	184.80
837	7700115	CEFOXITIN 0.6-1.5GM	184.80
838	7700115	CEFOXITIN 0.6-1.5GM	184.80
839	7700115	CEFOXITIN 0.6-1.5GM	184.80
840	7700115	CEFOXITIN 0.6-1.5GM	184.80
841	7700115	CEFOXITIN 0.6-1.5GM	184.80
842	7700115	CEFOXITIN 0.6-1.5GM	46.20
843	7700115	CEFOXITIN 0.6-1.5GM	184.80
844	7700116	CEFOXITIN 1.6-2.5GM	159.15
845	7700179	GENTAMYCIN AD 61-90M	36.49
846	7700179	GENTAMYCIN AD 61-90M	72.98
847	7700179	GENTAMYCIN AD 61-90M	72.98
848	7700179	GENTAMYCIN AD 61-90M	36.49
849	7700179	GENTAMYCIN AD 61-90M	109.47
850	7700179	GENTAMYCIN AD 61-90M	109.47
851	7700179	GENTAMYCIN AD 61-90M	72.98
852	7700181	GENTAMYCIN AD 121-15	110.46
853	7700190	PHARMACOKINETICS	220.00
854	7700506	DIAZEPAM 10MG INJ.	17.94
855	7700514	LEVORPHANOL 2MG INJ.	16.84
856	7700520	MEPERIDINE 50MG INJ.	16.35
857	7700520	MEPERIDINE 50MG INJ.	16.35
858	7700520	MEPERIDINE 50MG INJ.	16.35
859	7700520	MEPERIDINE 50MG INJ.	16.35
860	7700520	MEPERIDINE 50MG INJ.	16.35
861	7700520	MEPERIDINE 50MG INJ.	16.35
862	7700520	MEPERIDINE 50MG INJ.	16.35
863	7700520	MEPERIDINE 50MG INJ.	16.35
864	7700520	MEPERIDINE 50MG INJ.	16.35
865	7700520	MEPERIDINE 50MG INJ.	16.35
866	7700520	MEPERIDINE 50MG INJ.	16.35
867	7700520	MEPERIDINE 50MG INJ.	16.35

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OBS	CODE	DESCRP	CHARGES
868	7700520	MEPERIDINE 50MG INJ.	16.35
869	7700520	MEPERIDINE 50MG INJ.	16.35
870	7700520	MEPERIDINE 50MG INJ.	16.35
871	7700520	MEPERIDINE 50MG INJ.	16.35
872	7700520	MEPERIDINE 50MG INJ.	16.35
873	7700520	MEPERIDINE 50MG INJ.	16.35
874	7700520	MEPERIDINE 50MG INJ.	16.35
875	7700520	MEPERIDINE 50MG INJ.	16.35
876	7700520	MEPERIDINE 50MG INJ.	16.35
877	7700520	MEPERIDINE 50MG INJ.	16.35
878	7700520	MEPERIDINE 50MG INJ.	16.35
879	7700520	MEPERIDINE 50MG INJ.	16.35
880	7700520	MEPERIDINE 50MG INJ.	16.35
881	7700520	MEPERIDINE 50MG INJ.	16.35
882	7700520	MEPERIDINE 50MG INJ.	16.35
883	7700520	MEPERIDINE 50MG INJ.	16.35
884	7700520	MEPERIDINE 50MG INJ.	16.35
885	7700520	MEPERIDINE 50MG INJ.	16.35
886	7700520	MEPERIDINE 50MG INJ.	16.35
887	7700520	MEPERIDINE 50MG INJ.	16.35
888	7700520	MEPERIDINE 50MG INJ.	16.35
889	7700520	MEPERIDINE 50MG INJ.	16.35
890	7700520	MEPERIDINE 50MG INJ.	16.35
891	7700520	MEPERIDINE 50MG INJ.	16.35
892	7700520	MEPERIDINE 50MG INJ.	16.35
893	7700520	MEPERIDINE 50MG INJ.	16.35
894	7700520	MEPERIDINE 50MG INJ.	16.35
895	7700520	MEPERIDINE 50MG INJ.	16.35
896	7700520	MEPERIDINE 50MG INJ.	16.35
897	7700520	MEPERIDINE 50MG INJ.	16.35
898	7700520	MEPERIDINE 50MG INJ.	16.35
899	7700520	MEPERIDINE 50MG INJ.	16.35
900	7700520	MEPERIDINE 50MG INJ.	16.35
901	7700520	MEPERIDINE 50MG INJ.	16.35
902	7700520	MEPERIDINE 50MG INJ.	16.35
903	7700520	MEPERIDINE 50MG INJ.	16.35
904	7700520	MEPERIDINE 50MG INJ.	16.35
905	7700520	MEPERIDINE 50MG INJ.	16.35
906	7700520	MEPERIDINE 50MG INJ.	16.35
907	7700520	MEPERIDINE 50MG INJ.	16.35
908	7700520	MEPERIDINE 50MG INJ.	16.35
909	7700521	MEPERIDINE 75MG INJ.	16.38
910	7700522	MEPERIDINE 100MG INJ.	16.41
911	7700524	MORPHINE 10MG INJ.	16.49
912	7700524	MORPHINE 10MG INJ.	16.49
913	7700524	FLURAZEPAM 15MG CAPS	8.18
914	7700579	FLURAZEPAM 15MG CAPS	8.18
915	7700579	FLURAZEPAM 15MG CAPS	8.18
916	7700586	OPIMUM TINCT.DEOD. 1%	8.75
917	7700586	OPIMUM TINCT.DEOD. 1%	8.75
918	7700586	OPIMUM TINCT.DEOD. 1%	8.75

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OBS	CODE	DESCRP	CHARGES
919	7700586	OPIMUM TINCT. DEOD. 1%	8.75
920	7700586	OPIMUM TINCT. DEOD. 1%	8.75
921	7700651	PRIMARY SOLN-PLAIN	26.00
922	7700651	PRIMARY SOLN-PLAIN	26.00
923	7700651	PRIMARY SOLN-PLAIN	26.00
924	7700651	PRIMARY SOLN-PLAIN	26.00
925	7700651	PRIMARY SOLN-PLAIN	26.00
926	7700651	PRIMARY SOLN-PLAIN	26.00
927	7700651	PRIMARY SOLN-PLAIN	26.00
928	7700651	PRIMARY SOLN-PLAIN	26.00
929	7700652	PRIMARY SOLN-W/K+	26.00
930	7700652	PRIMARY SOLN-W/K+	26.00
931	7700652	PRIMARY SOLN-W/K+	26.00
932	7700652	PRIMARY SOLN-W/K+	26.00
933	7700653	IV SOLN W/MISC ADDIT	37.00
934	7700653	IV SOLN W/MISC ADDIT	37.00
935	7700653	IV SOLN W/MISC ADDIT	108.90
936	7700653	IV SOLN W/MISC ADDIT	108.90
937	7700653	IV SOLN W/MISC ADDIT	37.00
938	7700653	IV SOLN W/MISC ADDIT	108.90
939	7700653	IV SOLN W/MISC ADDIT	36.30
940	7700653	IV SOLN W/MISC ADDIT	108.90
941	7700653	IV SOLN W/MISC ADDIT	36.30
942	7700653	IV SOLN W/MISC ADDIT	74.00
943	7700653	IV SOLN W/MISC ADDIT	73.20
944	7700653	IV SOLN W/MISC ADDIT	36.60
945	7700653	IV SOLN W/MISC ADDIT	72.90
946	7700653	IV SOLN W/MISC ADDIT	36.30
947	7700653	IV SOLN W/MISC ADDIT	72.70
948	7700653	IV SOLN W/MISC ADDIT	72.60
949	7700653	IV SOLN W/MISC ADDIT	73.10
950	7700653	IV SOLN W/MISC ADDIT	72.60
951	7700653	IV SOLN W/MISC ADDIT	37.00
952	7700653	IV SOLN W/MISC ADDIT	72.70
953	7700653	IV SOLN W/MISC ADDIT	109.65
954	7700653	IV SOLN W/MISC ADDIT	109.20
955	7700653	IV SOLN W/MISC ADDIT	109.05
956	7700653	IV SOLN W/MISC ADDIT	36.35
957	7700653	IV SOLN W/MISC ADDIT	111.00
958	7700653	IV SOLN W/MISC ADDIT	72.60
959	7700653	IV SOLN W/MISC ADDIT	109.05
960	7700653	IV SOLN W/MISC ADDIT	36.30
961	7700653	IV SOLN W/MISC ADDIT	109.05
962	7700653	IV SOLN W/MISC ADDIT	72.60
963	7700653	IV SOLN W/MISC ADDIT	72.60
964	7700653	IV SOLN W/MISC ADDIT	109.05
965	7700653	IV SOLN W/MISC ADDIT	217.80
966	7700653	IV SOLN W/MISC ADDIT	109.05
967	7700653	IV SOLN W/MISC ADDIT	126.45
968	7700653	IV SOLN W/MISC ADDIT	109.05
969	7700653	IV SOLN W/MISC ADDIT	72.60

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OBS	CODE	DESCR	CHARGES
970	7700653	IV SOLN W/MISC ADDIT	109.05
971	7700653	IV SOLN W/MISC ADDIT	84.40
972	7700653	IV SOLN W/MISC ADDIT	36.60
973	7700653	IV SOLN W/MISC ADDIT	109.05
974	7700653	IV SOLN W/MISC ADDIT	111.00
975	7700653	IV SOLN W/MISC ADDIT	111.00
976	7700653	IV SOLN W/MISC ADDIT	36.85
977	7700653	IV SOLN W/MISC ADDIT	36.30
978	7700653	IV SOLN W/MISC ADDIT	108.00
979	7700653	IV SOLN W/MISC ADDIT	37.00
980	7700653	IV SOLN W/MISC ADDIT	84.00
981	7700653	IV SOLN W/MISC ADDIT	36.45
982	7700653	IV SOLN W/MISC ADDIT	36.30
983	7700752	DRUGS - CPR	425.00
984	7700821	FAT EMULSION 10% 500	77.10
985	7700821	FAT EMULSION 10% 500	77.10
986	7700821	FAT EMULSION 10% 500	77.10
987	7700825	TPN SOLN PEDIATRIC	1015.00
988	7700871	CIMETIDINE PREP 151-	76.84
989	7700871	CIMETIDINE PREP 151-	115.26
990	7700871	CIMETIDINE PREP 151-	115.26
991	7700871	CIMETIDINE PREP 151-	115.26
992	7700871	CIMETIDINE PREP 151-	38.42
993	7700871	CIMETIDINE PREP 151-	38.42
994	7700871	CIMETIDINE PREP 151-	76.84
995	7700871	CIMETIDINE PREP 151-	76.84
996	7700909	UNIT DOSE SUPPLY TOP	22.00
997	7700919	UNIT DOSE SOLID PREP	5.00
998	7700923	UNIT DOSE SOLID 0-.5	9.50
999	7700923	UNIT DOSE SOLID 0-.5	9.50
1000	7700923	UNIT DOSE SOLID 0-.5	11.40
1001	7700923	UNIT DOSE SOLID 0-.5	34.20
1002	7700923	UNIT DOSE SOLID 0-.5	11.40
1003	7700923	UNIT DOSE SOLID 0-.5	19.00
1004	7700923	UNIT DOSE SOLID 0-.5	5.70
1005	7700939	ADULT UD LIQ 0-.50	17.10
1006	7700939	ADULT UD LIQ 0-.50	11.40
1007	7700939	ADULT UD LIQ 0-.50	19.00
1008	7700939	ADULT UD LIQ 0-.50	5.70
1009	7700939	ADULT UD LIQ 0-.50	11.40
1010	7700939	ADULT UD LIQ 0-.50	3.80
1011	7700939	ADULT UD LIQ 0-.50	7.60
1012	7700939	ADULT UD LIQ 0-.50	68.40
1013	7700939	ADULT UD LIQ 0-.50	62.70
1014	7700940	ADULT UD LIQ .51-1.0	76.80
1015	7700940	ADULT UD LIQ .51-1.0	14.40
1016	7700958	ADULT IMJ 0-1.00	11.00
1017	7700958	ADULT IMJ 0-1.00	11.00
1018	7700958	ADULT IMJ 0-1.00	11.00
1019	7700958	ADULT IMJ 0-1.00	11.00
1020	7700958	ADULT IMJ 0-1.00	33.00

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OBS	CODE	DESCRP	CHARGES
1021	7700958	ADULT INU 0-1.00	11.00
1022	7700959	ADULT INU 1.01-2.00	12.00
1023	7700961	ADULT INU 3.01-4.00	14.00
1024	7700980	IMED CASSETTE/PUMP (	70.00
1025	7700981	IMED CASSETTE (ADULT	16.00
1026	7700986	IMED CASSETTE/PUMP 4	67.00
1027	7700986	IMED CASSETTE/PUMP 4	268.00
1028	7700986	IMED CASSETTE/PUMP 4	67.00
IDENT			66057.45

IDENT=03719499

OBS	CODE	DESCRP	CHARGES
1029	0008401	D6 IC DSC MEDICINE	960.00
1030	0016820	URIMETER	22.00
1031	0016896	ADMISSION KIT	11.00
1032	0018510	STANDARD 12 LEAD E.K	50.00
1033	0024247	BLOOD GAS ANALYSIS	55.00
1034	0024247	BLOOD GAS ANALYSIS	55.00
1035	0024247	BLOOD GAS ANALYSIS	55.00
1036	0024247	BLOOD GAS ANALYSIS	55.00
1037	0024247	BLOOD GAS ANALYSIS	55.00
1038	0024430	INTENSIVE RESP. THER	272.00
1039	0043172	ELECTROLYTES SERUM-S	31.25
1040	0043250	DIRECT BILIRUBIN	15.00
1041	0043314	ALKALINE PHOSPHATASE	25.00
1042	0043315	BILIRUBIN-TOTAL, SERU	17.25
1043	0043317	BLOOD UREA NITROGEN	20.50
1044	0043398	PROTEIN-URINE/FLUID	15.00
1045	0043402	AMMONIA	68.00
1046	0043405	GLUCOSE, NDNFASTING	12.00
1047	0043422	LACTIC DEHYDROGENASE	19.50
1048	0043422	LACTIC DEHYDROGENASE	19.50
1049	0043441	TOTAL PROTEIN	15.00
1050	0043442	SGOT-TRANSAMINASE-ST	25.00
1051	0043457	GLUCOSE-URINE/FLUID	13.00
1052	0043477	CALCIUM-SERUM, STAT	20.50
1053	0043485	CREATININE-SERUM-STA	17.25
1054	0043505	GLUCOSE NONFASTING-N	17.25
1055	0043516	CREATINE PHOSPHORINA	26.00
1056	0043522	LDH-LACTIC DEHYDROCE	25.00
1057	0043526	LACTIC ACID	33.50
1058	0043537	SGPT TRANSAMINASE ST	25.00
1059	0043562	MAGNESIUM SERUM STAT	28.00
1060	0043678	PROCAINAMIDE/NAPA	45.00
1061	0043695	DIGOXIN	48.75
1062	0047206	CYTOTOLOGY: BODY FLUID	79.03
1063	0053311	BLOOD COUNT (CBC) -	20.00
1064	0053315	DIFFERENTIAL - STAT	23.00

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OBS	CODE	DESCRP	CHARGES
1065	0053402	APT-STAT	20.00
1066	0053452	BODY FLUID CELL COUN	25.00
1067	0053469	PLATELET COUNT - STA	18.50
1068	0053518	PT-STAT	20.00
1069	0058295	FUNGUS EXAM	41.00
1070	0058295	FUNGUS EXAM	41.00
1071	0058332	AFB	60.00
1072	0058464	RESP. CULTURE-UPPER	39.00
1073	0058473	BODY FLUID CULTURE	38.00
1074	0091581	MEDICARE PAYMENT	3618.47
1075	0996789	MEDICARE PAYMENT	2602.35
1076	0997785	MEDICARE PAYMENT	5631.03
1077	7700651	PRIMARY SOLN-PLAIN	26.00
1078	7700651	PRIMARY SOLN-PLAIN	26.00
1079	7700752	DRUGS - CPR	426.40
IDENT			14927.03

IDENT=03734266

OBS	CODE	DESCRP	CHARGES
1080	0008401	D6 IC DSC MEDICINE	960.00
1081	0010238	C.T. BRAIN SCAN	380.00
1082	0016606	HYPOTHERMIA(DAILY US	90.00
1083	0016650	KIT HYPERALIMENTATIO	15.00
1084	0016820	URIMETER	22.00
1085	0016824	TRAY, CATHETER WITHO	18.00
1086	0016898	ADMISSION KIT	11.00
1087	0016977	ANESTHESIA EXTENSION	10.65
1088	0016979	DIAL-FLO	13.50
1089	0016979	DIAL-FLO	13.50
1090	0024430	INTENSIVE RESP. THER	272.00
1091	0024430	INTENSIVE RESP. THER	272.00
1092	0028150	EMERGENCY DEPT. VISI	59.00
1093	0030017	FRESH FROZEN PLASMA	60.00
1094	0030498	TYPE AND SCREEN	65.00
1095	0043172	ELECTROLYTES SERUM-S	31.25
1096	0043172	ELECTROLYTES SERUM-S	31.25
1097	0043172	ELECTROLYTES SERUM-S	31.25
1098	0043205	LDH ISOENZYMES	72.00
1099	0043261	ELECTROLYTES-URINE-S	28.00
1100	0043314	ALKALINE PHOSPHATASE	25.00
1101	0043315	BILIRUBIN-TOTAL, SERU	17.25
1102	0043317	BLOOD UREA NITROGEN	20.50
1103	0043317	BLOOD UREA NITROGEN	20.50
1104	0043322	CPK ISOENZYMES	75.00
1105	0043442	SGOT-TRANSAMINASE-ST	25.00
1106	0043463	AMYLASE SERUM STAT	25.00
1107	0043477	CALCIUM-SERUM, STAT	20.50
1108	0043485	CREATININE-SERUM-STA	17.25

THE UNIVERSITY OF CHICAGO HOSPITALS AND CLINICS
DETAILED CHARGES FOR CARDIAC ARREST PATIENTS
JULY 1984 - DECEMBER 1984

16:03 TUESDAY, AUGUST 20, 1985 23

21000

OBS	CODE	DESCRP	CHARGES
1109	0043485	CREATININE-SERUM-STA	17.25
1110	0043496	OSMOLALITY-SERUM-STA	27.00
1111	0043504	GLUCOSE FASTING-FBS	17.25
1112	0043505	GLUCOSE NONFASTING-N	17.25
1113	0043516	CREATINE PHOSPHORINA	26.00
1114	0043522	LDH-LACTIC DEHYDROGE	25.00
1115	0043536	OSMOLALITY-URINE-STA	27.00
1116	0043537	SGPT TRANSAMINASE ST	25.00
1117	0043562	MAGNESIUM SERUM STAT	28.00
1118	0043626	TOXICOLOGY PANEL	50.00
1119	0043667	LIDOCAINE	40.00
1120	0044233	CIRCULATING ANTICOAG	86.00
1121	0044302	APT	19.00
1122	0044364	LUPUS ANTICOAGULANT	80.00
1123	0044418	PROTHROMBIN TIME	16.00
1124	0044563	FACTOR VIII ASSAY	80.00
1125	0044579	FACTOR VIII INHIBITO	104.00
1126	0053218	BLEEDING TIME	21.00
1127	0053311	BLOOD COUNT (CBC) -	20.00
1128	0053315	DIFFERENTIAL - STAT	23.00
1129	0053402	APT-STAT	20.00
1130	0053402	APT-STAT	20.00
1131	0053469	PLATELET COUNT - STA	18.50
1132	0053518	PT-STAT	20.00
1133	0053518	PT-STAT	20.00
1134	0094900	INSURANCE ESTIMATE-C	6687.35
1135	7700651	PRIMARY SOLN-PLAIN	26.00
1136	7700651	PRIMARY SOLN-PLAIN	26.00
1137	7700651	PRIMARY SOLN-PLAIN	26.00
1138	7700651	PRIMARY SOLN-PLAIN	26.00
1139	7700651	PRIMARY SOLN-PLAIN	26.00
1140	7700651	PRIMARY SOLN-PLAIN	26.00
1141	7700651	PRIMARY SOLN-PLAIN	26.00
1142	7700651	PRIMARY SOLN-PLAIN	26.00
1143	7700651	PRIMARY SOLN-PLAIN	26.00
1144	7700761	LIDOCAINE PREP O-2GM	36.70
IDENT			10506.70

IDENT-03767779

OBS	CODE	DESCRP	CHARGES
1145	0003201	BLOOD GAS ANALYSIS	55.00
1146	0003504	HEMODYNAMIC MONITORI	102.50
1147	0003706	ANES. 4 HR. LESS THA	1105.00
1148	0005401	D4 IC DSC SURGERY	960.00
1149	0005401	D4 IC DSC SURGERY	960.00
1150	0005401	D4 IC DSC SURGERY	960.00
1151	0005401	D4 IC DSC SURGERY	960.00
1152	0005401	D4 IC DSC SURGERY	960.00

IDFNT-03767779

OBS	CODE	DESCRP	CHARGES
1153	0008401	D6 IC DSC MEDICINE	960.00
1154	0008401	D6 IC DSC MEDICINE	960.00
1155	0010017	CHEST - P/A AND LATE	77.00
1156	0010017	CHEST - P/A AND LATE	77.00
1157	0010095	CHEST - SINGLE VIEW	59.00
1158	0010095	CHEST - SINGLE VIEW	59.00
1159	0010095	CHEST - SINGLE VIEW	59.00
1160	0010095	CHEST - SINGLE VIEW	59.00
1161	0010095	CHEST - SINGLE VIEW	59.00
1162	0010095	CHEST - SINGLE VIEW	59.00
1163	0010095	CHEST - SINGLE VIEW	59.00
1164	0010095	CHEST - SINGLE VIEW	59.00
1165	0010095	CHEST - SINGLE VIEW	59.00
1166	0010095	CHEST - SINGLE VIEW	59.00
1167	0010095	CHEST - SINGLE VIEW	59.00
1168	0010104	NEEDLE BIOPSY	319.00
1169	0010106	EXAM AT BEDSIDE OR 0	54.00
1170	0010106	EXAM AT BEDSIDE OR 0	54.00
1171	0010106	EXAM AT BEDSIDE OR 0	54.00
1172	0010106	EXAM AT BEDSIDE OR 0	54.00
1173	0010106	EXAM AT BEDSIDE OR 0	54.00
1174	0010106	EXAM AT BEDSIDE OR 0	54.00
1175	0010106	EXAM AT BEDSIDE OR 0	54.00
1176	0010106	EXAM AT BEDSIDE OR 0	54.00
1177	0010106	EXAM AT BEDSIDE OR 0	54.00
1178	0010106	EXAM AT BEDSIDE OR 0	54.00
1179	0010106	EXAM AT BEDSIDE OR 0	54.00
1180	0010150	ABDOMEN SINGLE VIEW	85.00
1181	0010706	CT SCAN-PELVIS W/O 1	464.00
1182	0010715	CT SCAN-ABDOMEN W/O	464.00
1183	0016555	EQUIP. PURCHASED OUT	104.00
1184	0016508	SUCTION-CHEST, PORTAB	41.00
1185	0016609	SUCTION-GASTRIC, PORT	40.00
1186	0016650	KIT HYPERALIMENTATIO	15.00
1187	0016650	KIT HYPERALIMENTATIO	15.00
1188	0016721	SET, STITCH	26.00
1189	0016721	SET, STITCH	26.00
1190	0016721	SET, STITCH	26.00
1191	0016803	SUCTION, WOUND(VACUUR	63.00
1192	0016804	IRRIGATION SET-GENER	6.00
1193	0016804	IRRIGATION SET-GENER	6.00
1194	0016804	IRRIGATION SET-GENER	6.00
1195	0016804	IRRIGATION SET-GENER	6.00
1196	0016811	KITS, SUCTION CATHETE	20.00
1197	0016811	KITS, SUCTION CATHETE	20.00
1198	0016811	KITS, SUCTION CATHETE	40.00
1199	0016824	TRAY, CATHETER WITHO	18.00
1200	0016850	JACKSON PRATT DRAIN	54.00
1201	0016898	ADMISSION KIT	11.00
1202	0016904	BIOD COMPONENT FENA	5.00
1203	0016912	SODIUM CHLOR IRRIG 9	5.00

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IV. The Decision Not to Resuscitate

Since 1960, when research demonstrated that external cardiac massage could be used to restore circulation in a patient without heart beat,¹ basic CPR has been used widely — first in post-operative cardiac arrest victims, and later in many different patients in the general hospital population. In this general population, the presumption had been to resuscitate all patients with cardiac or respiratory arrest. The prevailing professional attitude favoring prolongation of life whenever possible had been reflected in the relative rarity of orders not to resuscitate. Until recently there has been a paucity of publicized and published discussion about such decisions in professional journals and meetings.

In most nursing homes, in contrast, the presumption had been to not resuscitate. Proper equipment was not present and staff were not trained. A common practice had been to transfer ill nursing home residents to an acute care hospital where, if cardiac arrest occurred, the patient would be resuscitated. Thus, the decision about resuscitation had not been a deliberate or direct one, and the patient's location (nursing home or hospital) determined resuscitation status rather than medical indications, patients choice, or other factors.

The use of orders not to resuscitate (DNR orders) has evolved gradually. In 1974, fourteen years after the first report of a series of CPR in hospital the American Medical Association recommended no CPR "... in cases of terminal irreversible illness where death is expected."² In 1976, initial policies concerning DNR orders were published by several prominent Boston hospitals^{3,4} but not widely accepted. While decisions not to resuscitate were being made, physicians were reluctant to make them explicit or written, partly in fear of possible liability ramifications.

Since 1976, DNR orders have been written and interpreted differently by different institutions. Although a specific hospital's policy will often specify the need for

involvement of the attending physician, an attorney, the patient or the patient's family in this decision, the policy will less often ask that the physician describe precisely what therapy will not be undertaken. "Do Not Hospitalize" orders have recently been described⁵ to appear in the charts of some nursing home residents. Do Not Intubate orders may be implied by DNR orders but are seldom explicit. The use of cardiac pressor agents, blood and volume replacement and antibiotics are often not thought of as resuscitation, though they are life-sustaining.

Orders not to resuscitate most often mean restraint from chest compression and cardioversion in the event of a cardiac or respiratory arrest. Mechanical ventilation and cardiac pressors may or may not be used; blood transfusion and volume replacement are often continued. Only some DNR orders actually specify what is not to be done, although this information may be found in another part of the medical record. In the frequently encountered case of a dying but intubated patient, in whom a DNR order has just been written, care is seldom withdrawn: ICU resource utilization before and after a written DNR order was comparable in one large study of ICU patients.⁶

In teaching hospitals, attending physicians usually write DNR orders if they are to be written.⁷ As many providers care for a patient, and housestaff often have primary patient care responsibility, a senior resident may sometimes write a DNR order as a verbal order from the attending physician to be co-signed within 24 hours by the attending physician. In most instances, however, physicians do not ask the patient's opinion, even if he is able to participate in the decision.⁸ Indeed, the family is more likely to be directly consulted than the patient.⁹ In the limited studies identifying decision makers, social workers and chaplains have been found to be uninvolved.⁸ In institutions without policies, housestaff seemed to make these decisions, without documented attending physician consultation.¹⁰

Decisions in the community and in nursing homes have not been extensively studied, but one questionnaire case study shows community physicians to be more aggressive

in approach than attending physicians and housestaff.¹¹ Nurses may play a significant part in DNR decisions, and are thought by many gerontologists to have a large role in the elderly patient's case, especially those nurses in nursing homes. Little direct evidence for or against this observation exists, however.

Many caretakers feel that "indiscriminate applications (of CPR) may reflect poor clinical judgment" in nursing home patients. Half of 153 competent elderly female nursing home residents, when prospectively surveyed, would choose not to have CPR, while less than 10% would choose to have it.¹² Indeed, it has been suggested that community-wide policies be established in which CPR be limited to witnessed arrest of patients, with their physicians required to write and review the pertinent order for or against resuscitation every two years.¹³

DNR decisions in hospitals are often made in the cases of very ill patients. Factors important in making these decisions may include the stated policy of the institution, but more commonly include the patient's long term prognosis, the efficacy or futility of further treatment, the patient's quality of life and previous DNR order, if any.¹⁴

Estimated probability of arrest and treatment location in the hospital have not been proven to influence decision making. In combination with chronicity and multiplicity of illness, advanced age clearly does influence these decisions. In some studies age by itself may influence decision making. Among 62 surveyed housestaff members, patients age 64 and 98 were less likely to be resuscitated than a patient age 32 with the same medical problem.¹⁵

Advanced age alone is not a reliable predictor of either survival or level of functioning after CPR. Much of this less aggressive approach to resuscitation may stem from physician inferences about the poor quality of life of the elderly, chronically ill patient. Patients themselves are rarely asked about a DNR decision. Physicians may feel that they already know what the patient, particularly a reticent, poorly communicative patient desires, and often do not ask. They may, on the other hand, feel it is unethical not

to attempt resuscitation since to withhold it is certain death, or since the patient may (only) have multiple medical illnesses and no clear "terminal" disease.

Differences in DNR decision making between tertiary and primary care facilities, county, community hospitals and VA hospitals, and between urban and rural hospitals have not been studied, though it has been observed that scarcity or abundance of resources can influence these decisions. Little documented evidence exists to support this observation. One study in a county hospital found that the patient payment status had no significant association with DNR orders, nor did age alone have an independent correlation. Cognitive impairment, and other "quality of life" measures did have a significant correlation.¹⁶

DNR orders in Intensive Care Units (ICU) have been of great interest. Resource utilization is greater in the ICU than on the wards. A year-long national survey of 13 teaching hospitals showed an average of 14% of ICU patients had DNR orders. 87% of these 199 patients stayed in the ICU less than 3 days after DNR orders were written, implying withdrawal of this aggressive and intensive technical intervention.¹⁷ There is evidence in the ICU that DNR orders are being written earlier now than several years ago suggesting both improved prognostic information and increasing physician acceptance of that information.¹⁸ Futility of treatment is commonly cited.¹⁹ Even in hospitals with policies encouraging the writing of explicit DNR orders, there is documentation of the reasoning for the order in barely more than 1/2 of the cases. Discussion with patient or family usually occurs, but is by no means universal.⁶

Consent and competency have a special interrelation in the elderly. Traditionally, patient autonomy and self determination have been guidelines in medical care. These principles of individual decision making apply in all circumstances except those in which the patient is unable to communicate or judge for himself what he prefers. This clinical definition of competency differs from the legal definition, which may become especially important in emergent clinical settings. Reversible causes of incompetency, such as

acute illness, particularly in the elderly, or irreversible causes, such as many types of dementia, may cause an abnormal, altered mental status. Here we consider only the irreversible causes and conditions of abnormal mental status.

Up to 60% of patients with DNR orders may be mentally incompetent and be unable to participate in the resuscitation decision.²⁰ If the patient is incompetent some DNR hospital policies require family concurrence with the physician decision in order for a DNR order to be written.²¹ It has been clearly shown that even with competent patients, physicians speak with families more often than with the patient himself. In competent patients, many physicians would prefer to rely solely on medical indications for treatment, although the definition and parameters of medical futility often are uncertain. Information may be unknown or assessment of quality of life may confound clinical assessment and treatment. Medical indication may become blurred by family or peer pressure.

Terminally ill competent patients who wish maximum treatment often receive it. Terminally ill competent patients whose families wish maximum treatment for them may receive it. Terminally ill incompetent patients without families have not been studied, but indications for treatment may vary with the setting. The wishes and contribution of the family are clearly important. In DNR decisions discussion with the family requires tact, sensitivity and clarity from health care providers. While the physician may feel more comfortable with a decision "made by the family", it is not an easy decision for family members to make and may be influenced by past dynamics of their relationship. A daughter who feels guilty that she had neglected her father may ask the physician to do everything possible to keep him alive. This request may make her feel better but may not represent his wishes. Conversely, a daughter who cannot stand the idea of infirmity and disability for herself may ask the physician "not to prolong his suffering", which also may not represent the older persons real wishes.

Disagreements may occur between family and physician about DNR orders, and may result in verbal DNR orders from one caretaker to another, without family consent.¹⁴ The standard of practice, however, is routine resuscitation. Physicians are especially reluctant to record DNR orders when there is disagreement, as there is fear of litigation, even when medical indications are clear. In many such instances no DNR order is written; if the patient arrests, CPR is performed "for the benefit of the family".¹⁴ These patients do not always arrest, however, and may in fact survive.

Intended to rank humanity above technology, DNR orders have many utilities. Guidelines recommend that DNR orders may be written if further medical treatment is futile and/or the competent patient does not wish CPR. In the critically ill ICU patient, DNR orders may serve as a statement that the patient's condition is hopeless, allowing the physician to withdraw certain technologies such as intensive care.¹⁷ Here the DNR order may be used to sanction imminent death. There is little evidence that the use of resources within intensive care units, such as mechanical ventilation, antibiotics and nutrition are modified in the ICU as a result of a DNR order. In this prospective study,⁶ vigorous medical treatment, employed to treat concomitant reversible illnesses, continued to be undertaken at the same level.⁶

Though DNR orders should not connote abandonment, it is clinically observed that caretakers tend to withdraw from these patients. Because these patients are often dying, physicians may find it difficult to develop a physician-patient relationship.²² The physician may skip the patient on rounds yet allow technological intervention to continue as a surrogate for patient care. However, the goals of therapy may change with a DNR order, from one of cure to one of comfort for both patient and family. As the primary goal of patient comfort is nontraditional, physicians and even sometimes nurses may have difficulty in recognizing it as valid.

It is unknown to what degree actual practice coincides with stated policy of any given institution. Every house officer has experienced a "slow code" - a management

option when an explicit DNR order cannot be written (e.g., the family, the patient or the attending physician do not agree) or when the resident himself is uncomfortable with the order. This is called a "slow code" because the house officer will say to the intern on call "If the patient arrests, walk, don't run". Another version is that he may ask the nurses to page him personally rather than alert the CPR team over the loudspeaker. In both cases, this is "going through the motions" with the impression that the patient won't survive. It is often a self-fulfilling prophecy however, because in order to be effective, CPR must be instituted with all possible speed. A "slow code" may be more likely to produce a survivor with permanent brain damage than no survivor at all. Partial, limited or "slow" codes, thought to be a "kind of dishonest effort" and to reflect "provider discomfort in discussing DNR decisions"²³ still occur, though little documentation of these exists. In one study, 43 percent of medical housestaff would provide less than full resuscitation of their "seriously ill but DNR not discussed yet inpatients".¹⁰ Needless to say, housestaff and nurses are often confused about the specific care to be provided such patients. Nurses are particularly vulnerable here: if the intern gives a verbal, undocumented order to call him/her instead of the code team, the nurse may think of her/himself as legally liable for negligence. Thus, most authors and legal experts advise explicit decision making (DNR or not) and clear documentation of these decisions.

Documentation of DNR orders is widely variable. Most published hospital policies require documentation in the medical record of the factors contributing to and persons participating in the decision as well as a written doctor's order. In a decision of this magnitude, there is no place for informal or verbal orders. Hospital attorneys counsel that a carefully documented decision is less likely to be the subject of a malpractice suit than a poorly communicated, undocumented verbal order.

Physician fear of litigation, physician fear of bringing about worsening depression or pain,²⁴ and physician interest in placating other staff or family members are some of the reasons for nondocumentation of resuscitation status. One study of physician orders

show that no written justification exists in more than 40% of medical records. There is a strong association between a previous DNR order and, should the patient survive to leave the hospital, a second DNR order written on readmission.²⁵ In teaching hospitals without DNR policy, housestaff often write the orders, documented in approximately 60% of non-resuscitated patients, with "some form of documentation" present in 83%.¹⁰ In one study, 20% of competent patients were made DNR without their participation but with that of their family.

Advance decision making about resuscitation has distinct advantages. The purpose, nature, risks and common outcomes of CPR were described in written form to 163 Illinois institutionalized women, mean age 83. Their choices were made and recorded. Should she be hospitalized, a copy of her wishes regarding CPR is transferred with durable power of attorney to the physician caring for her in that institution.¹² In Minnesota, a county medical society recently endorsed an Emergency Medical Services Council Ethics Committee policy that requires nursing home physicians to write orders concerning resuscitation or intubation every two years, limiting pre-hospital emergency treatment.¹³

Some gerontologists have observed that wishes and outlooks concerning resuscitation may change throughout life with time and circumstance. However, there are no studies documenting this phenomenon. Hospital policies, especially those that respect advance directives such as "living wills", do recognize a presumption of the continuity of personal values over time.

Re-resuscitation has been used as a criterion to forego CPR in at least one study of CPR of the elderly (mean age 75).²⁶ In a second study²⁷ of 9 CPR survivors over age 60 six months after discharge from the hospital, 7 would not agree to another resuscitation, and two had no opinion. The authors did not report the reasons for this decision. In fact, all 9 claimed to be satisfied with their current life and state of health and to not remember the resuscitation. In another study of 38 competent survivors, 21 would choose resuscitation again and 16 would not; one was ambivalent.¹⁴

The elderly are more likely to have chronic illnesses and are more likely to be hospitalized than younger persons. Because of their higher consumption of medical resources, and greater amount of medical care required, special attention should be given to several concerns.

First, elderly patients, especially those with long standing chronic disease, may be of less than median socio-economic status. Medicare pays for much of their acute medical care, with reimbursement for hospitalization based on Diagnosis Related Groups. Physicians now have strong economic incentives to minimize hospitalization and particularly intensive care utilization, as reimbursement is fixed. Physicians may allocate resources in response to societal pressures to contain the cost of medical care by deciding who should receive expensive resources. While not extremely expensive itself (See Task II) resuscitation is thought to lead often to substantial use of intensive care and long term care resources, especially if recovery is only partial. The factual and moral basis for this is questionable, but physicians must presently operate without a clear clinical strategy.

Cost/benefit and socio-economic factors have been shown in one study to be integrated into physician decision making in a specific case in an elderly nursing home patient requiring intubation. In another study,¹¹ socio-economic and racial factors were not significant. Of 165 patients who died in a county hospital, no difference was observed between Medicare, MediCal, self-pay patients and third party insurance payers.¹⁶ Uninsured patients were not included in this analysis. DNR practice in County and VA facilities has not yet been compared with that of community facilities, of particular interest because community hospitals admit many fewer uninsured patients. If such patients must be admitted, they are commonly transferred to a county or VA facility when "medically stable", so DNR issues often do not have time to arise.

As the aged are more likely to have chronic illnesses, the definition of terminal and irreversible illness is especially difficult. Poorly responsive, ineffectively treated

cardiac, pulmonary, hepatic and renal disease, cancer, and other progressive disorders, including neurologic ones, can lead to death but with good care can be compatible with months to years of life. Mental illness, advanced age or the presence of multiple chronic illnesses are by themselves not grounds to write DNR orders. Mental decline is a "quality of life" issue which often arises in these decisions. Mental status change with acute illness, on a spectrum from lethargy to unconsciousness, affects the elderly more than any other age group, and therefore some degree of improvement in mental function is sometimes possible. The degree of chronic dementia, if present, is of particular importance to document, and the prior expressed wishes of the patient should be sought. Ethically justifiable reasons for orders not to resuscitate are 1) medical futility and 2) patients' wishes.²⁸ Since medical futility is often difficult to assess, many authors favor ascertaining the patient's choice at a time when the progression of disease has not yet interfered with the patient's decision-making capacity.

The circumstances surrounding DNR decisions are often extremely complex. Patient capacity to participate is often questionable. Physicians have difficulty discussing resuscitation and the possibility of death. Familial, financial and inferential considerations arise and are considered. Ethics consultants and committees may have a special role here.^{29,32} Professionals not directly involved in the patient's care but knowledgeable about clinical medicine and trained in medical ethics can help explore and clarify the issues in question. Ethics committees have served a useful similar role in decision-making about critically ill, severely impaired infants.³¹ In general, the more open and more thoroughly considered DNR decision the better the quality of those decisions.

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V. Resuscitation Policies

"In the making of decisions for the treatment of seriously deformed newborns or persons who are severely deteriorated victims of injury, illness, or advanced age, the primary considerations should be what is best for the individual patient and not the avoidance of a burden to the family or to society."¹

[Opinion of the AMA Judicial Council,
published as 48 Fed. Reg. 30, 846 (July 5,
1985)]

Resuscitation policies evolved in response to changes in medical capacity and have been developed by hospital, nursing homes, and hospices. As cardiopulmonary resuscitation became an increasingly successful medical intervention, policies about resuscitation were necessary. Prior to such technology, persons suffering from cardiac and respiratory arrest usually died, unaided by the sophisticated machinery and the highly trained medical personnel routinely available today. Training of medical personnel in life-saving resuscitation procedures has been given emphasis since the late 1960's. In 1968, the American Heart Association issued to hospitals an "Emergency Resuscitation Team Manual, Hospital Plan" to aid in establishing effective resuscitation procedures.

In 1974, the American Medical Association's House of Delegates approved a resolution "to educate all physicians, regardless of specialty, in the techniques of cardiopulmonary resuscitation". For the next several years, the medical profession and, to some extent, the public enthusiastically sponsored CPR training programs in hospitals and in communities. Activity has diminished somewhat since 1980, partly because of lessened enthusiasm about the outcomes of such widespread public training (See Chapters 1 and 2).

Advances in medical technology have prompted discussion about whether to forego the use of CPR in some instances. Issues and considerations such as quality of life, whether to treat, and the right to die arose because technology afforded treatment possibilities, alternatives, and choices. Physicians and patients were confronted with choosing not only among alternative regimens but, also, whether to treat at all. Quality of life issues and the rights of patients figured significantly in the debate.

Advances in medical technology are a component of the need for resuscitation policies. Patient awareness and input into medical decisions is another factor. The Karen Ann Quinlan case set a legal precedent, recognizing that patients have a legal "right to privacy".¹² This right has become the basis by which patients and guardians can refuse medical treatment and intervention. Commentators cite the case as a milestone as it signaled a change in medicine, law, and ethics. (See Chapter VII). It was the impetus for right to die discussion and for living will legislation; the case also provided a foundation for development of resuscitation policies and the use of ethics committees.

As patients took a more active role in medical decision making, treatment choices could no longer be left solely to the discretion of the hospital, medical staff, attending physician, or family doctor. Medical decision making is today redefined, with broader parameters which incorporate the wishes of the patient. Proponents of patient input advocate such involvement as a way to facilitate dialogue between physician and patient.

This dialogue is not the whole answer to the problem of decision making about life sustaining measures. Many patients are uncomfortable with making decisions about their treatment. Many physicians are uneasy about sharing complex and technical decision making since they see themselves as having final legal responsibility. For medical decision making on a daily basis, there is a need for mechanisms by which physicians and patient can reach consensus about clinical matters. One response to this need is the adoption of guidelines, statements and policies governing an array of medical issues, including cardiopulmonary resuscitation. The institutional policy issue that arises in relation to CPR is the handling of decisions not to resuscitate. (See Chapter IV).

Early policies often were not explicit enough, or they were poorly designed. Eventually, medical associations, hospitals, and other entities established more systematic guidelines, frequently in response to location situations and individual cases that arose often in legal procedures. Specified mechanisms have gradually replaced haphazard approaches. The trend is toward development and adoption of policies specifying the principles of decision making relevant parties to the decision and practical implementation.

Hospital Associations

A number of national hospital associations and organizations were contacted, none of which themselves have resuscitation guidelines or policies, and none have issued policy statements to member hospitals. Most hospital associations do not see it as within their purview to offer guidelines, establish policies, or issue policy statements, but they will support their member hospitals by providing information or facilitating communication between institutions.

A representative of the American College of Osteopathic Hospital Administrators (ACOHA) did indicate that the association regularly polls member hospitals for information, changes, trends, and quality assurance. The representative expressed willingness to incorporate into future ACOHA survey instrument questions about resuscitation guidelines. We have sent sample questions to the ACOHA.

The Joint Commission on the Accreditation of Hospitals is in the process of surveying a national sample of acute care hospitals, psychiatric hospitals, and long-term care facilities about their resuscitation policies. The JCAH survey is in response to the 1983 President's Commission recommendation that "in order to be accredited hospitals should be required to have a general policy regarding resuscitation".²⁴ The Commission suggested that the JCAH study the need for general accreditation standards for resuscitation policies.

Drafts of the JCAH questionnaire have been drawn up and being pretested. Input, comments, and suggestions from pre-testing will be incorporated into the final questionnaire. Results will be available in spring, 1986.

The Veterans Administration has developed resuscitation standards to guide member institutions in formulating policies tailored to the population served by each facility. The VA system includes acute care hospitals, rehabilitation institutes, psychiatric hospitals, and long-term care programs, and resuscitation policies for such diverse facilities will reflect the range of services provided by them.

Hospital associations from 34 states participated in our study. State hospital associations are not involved in the clinical decisions of their member hospitals, yet 59% of respondents have a set of guidelines regarding resuscitation, act as a clearinghouse for policy information, or are currently drafting some form of model resuscitation policy to guide hospitals in developing their own institutional standards. 25% of these state associations have formal, written resuscitation policies.

Literature review and telephone survey findings on religious hospital associations are that most of them do not offer resuscitation guidelines, have established policies, or issue policy statements to member hospitals. An important exception is the Catholic Hospital Association (CHA) which has distributed a publication entitled To Treat or Not Treat. Catholic hospitals have been leaders in the movement for humane quality care of dying patients, and thus have had to consider the resuscitation question in that context. Their work have provided leadership for many in hospice work and palliative care. The Protestant Hospital Association indicates that the CHA resuscitation guidelines are under consideration for use by its association, indicating agreement on the basic issues across Christian groups. Jewish hospitals are likewise developing guidelines for DNR orders, but seem to be doing so independently rather than as a group.

Individual Hospitals

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A study surveying five midwestern states for resuscitation policy provides statistics on the number of hospitals with resuscitation policies and discusses the prevalence of institutional ethics committees. The paper is under editorial review for journal publication and is not available for citation here. The results of the study will likely be a significant addition to our telephone survey findings and suggests that institutions are assessing the prevalence and composition of policies about resuscitation.

Among the hospitals whose resuscitation policies we examined, several have DNR (do not resuscitate) guidelines which have been in operation for two or more years; some have no policy. One 433-bed not-for-profit hospital established a written resuscitation policy in 1983.¹¹ This policy was developed by a resuscitation committee with input from and eventual adoption by the medical staff. Included in the statement are definitions of key terms and specification of responsibilities of medical personnel in respect to DNR orders. The policy does not incorporate an ethics committee, it is reviewed annually, and it is working satisfactorily.

Another 1983 resuscitation policy, written by the risk manager with input from a multi-disciplinary committee and approval by the medical board, is in place at one multi-level institution. The family and the patient, if competent, are consulted. There is a presumption to resuscitate in the absence of an order to the contrary. The DNR order is reviewed every 48 hours except in the skilled nursing facility where DNR renewal is on a weekly basis. Although the resuscitation policy does not require annual review, it has undergone two reviews since implementation in 1983. This is a broad statement which covers DNR and other termination of treatment issues.

One 343-bed church-operated hospital has a policy developed by an ad hoc committee, consisting of a lawyer, a priest, hospital personnel, and members of the medical staff.⁵ Governing only resuscitation, the policy recognizes the right of each

individual to be "protected from the loss of dignity and the premature termination of life, as well as from extraordinary and unnatural prolongation of life when dying is irreversible". The policy defines terms prolongation of life when dying is irreversible". The policy defines terms ("ordinary means", "terminal patient", for instance), specifies informed consent, and requires written DNR orders. DRN designation must be reviewed frequently and reinstated weekly. It is reported to be working well.

In contrast to the hospitals with viable resuscitation policies is a 1,278-bed county hospital which has none. There is no ethics committee. A physician from this hospital is working on a study of resuscitation guidelines and policies in the Chicago area. Findings suggest that although many hospitals do not have written policies, it is a topic of current debate among medical and hospital professionals.

Nursing Home Associations

Contact with the American Association for Homes for the Aging, and the American Health Care Association reveals that both groups are surveying their members about nursing home resuscitation policies. (Results of the surveys may be available by Spring 1986). The American Health Care Association (AHCA) has published a pamphlet, "Health Care Decision Making in Long Term Care Facilities". This publication does not offer resuscitation policy and does not explicitly address resuscitation decision making. It is intended to serve as a guide to AHCA member nursing homes in health care decision making, stating that "because of wide differences in state law and rapidly changing state of the law within jurisdictions, the pamphlet does not attempt to provide specific guidance and should be considered only as a starting point in the development of specific policies and procedures..."⁴⁴ Believing that these issues can most appropriately be resolved at the state level, AHCA has developed the guidelines to assist its state affiliates and member facilities in establishing their own policies.

In general, nursing home associations and organizations do not offer specific policies regarding resuscitation and the elderly. The American Association of Homes for the Aging and the American Health Care Association do, however, issue broad policy statements which concern medical decision making such as that involved in resuscitation.

All nursing homes in our survey have some kind of resuscitation policy. Elements of policies include identification of the need for and purpose of the policy, definition of key terms, identification of treatment classifications (hospitalization with full support, hospital with DNR code, no hospitalization), and descriptions of responsibilities of physicians, nurses, and social service workers.

There is a sparse literature on resuscitation in nursing homes, but it is clear that nursing homes face difficulties unlike those of other health care facilities. First, nursing homes are often designed to be more like a home than a hospital, and highly technical medical interventions are not usually carried out in these settings. Second, with DRGs sicker patients are discharged to nursing homes and critical life-threatening illness is more likely to occur there. Third, some nursing home residents may not be candidates for CPR either because of their own expressed wishes or because of their medical condition. A growing problem is emergency treatment of DNR-designated nursing home patients in transit to hospitals. The situation imposes a dilemma for emergency health care providers because "standing orders" mandate resuscitation of patients - despite nursinghome DNR status. This suggests that even though a nursinghome recognizes DNR status of its residents, this may not be enough. Perhaps nursing home resuscitation policies should specify the level of emergency intervention should a nursing home resident require hospitalization.

Hospices

The literature review and telephone survey include both a hospice association and specific hospices, which are institutions and home care services directed towards the palliative care of patients with terminal disease. The National Hospice Association does not have a resuscitation policy or offer guidelines to member hospices. There is a monograph, "Decisions in Hospice", which may offer policy guidelines but the publication is not currently available. One may assume, however, that few if any people are resuscitated in a hospice setting.

There is little literature about resuscitation ethics committees, not surprising since both resuscitation policies and ethics committees are recent developments. Telephone survey findings on ethics committee indicate that one of the hospitals, nursing homes, or hospices in our study have both a resuscitation policy and an ethics committee.

This result conflicts with the findings in an unpublished paper in which the authors surveyed hospital resuscitation policies in five midwestern states. The data suggests that the existence of an ethics committee tends to be associated with the presence of a resuscitation policy. This has not been substantiated by our survey. It may be that since ethics committees and DNR policies deal with a number of the same issues, many institutions are comfortable having one or the other, and do not see the need for both mechanisms in managing treatment dilemmas.

Summary and Assessment

Few national associations and organizations have established resuscitation policies. Such policies are, generally, developed by individual hospitals, nursing homes and hospices. Among resuscitation guidelines in place, there is a variety of formats, consisting of a range of components. Ethics committees are not usually found in conjunction with resuscitation policies.

That so few national medical, hospital, nursing home, and hospice associations have established resuscitation policies has probably led individual hospitals, nursing homes and hospices to do so. With little national input, and no consistent legal parameters (see Chapter 7), institutions are afforded minimal guidance in developing guidelines.

Some formats and components may be more appropriate for one kind of institution than for another. For instance, hospitals and nursing homes serve different populations and provide different services and levels of care. In recognition of this, it seems reasonable to question whether there are core criteria for institutions to consider in developing resuscitation policies.

Elements of a Model Resuscitation Policy

Existing policies show considerable diversity, reflecting the range of emphasis among institutions and associations. Higher order guidelines (those of organizations which represent many member hospitals, for instance) should be adapted to the needs of particular institutions. Still, there are certain ethical and legal requirements which mandate the basic components of a good resuscitation policy.

The following elements of a DNR policy are those which have been found to comply with ethical and legal norms, and reflect general patterns in hospitals and nursing homes surveyed:

1. A statement that "orders to resuscitate" is a standing order in the institution and that this procedure should be initiated unless there is an expressed order to the contrary.

2. A statement regarding the patient's wishes.
3. A statement of the medical conditions which should be present to justify an order not to resuscitate.
4. A statement regarding the role of the family or close associates.
5. A statement regarding the entry of the DNR order in the patient's record.
6. A statement about the scope of the order, for example that a DNR order does not limit other forms of medical intervention.
7. A statement regarding the obligation of various persons responsible for the care of the patient.

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LEGAL ISSUES IN RESUSCITATION DECISIONS

Introduction

In order to discuss the legal issues involved in the decisions regarding resuscitation of elderly patients, it is necessary to place the entire topic in the context of medical realities and patients' rights. As other chapters of this report have made clear, age is not, and should not be, a factor in determining whether to resuscitate a patient in the event of an acute cardiac episode. The medical condition of the particular patient and the patient's wishes are the determining factors in such a decision.

Other sections of the report discuss medical conditions and outcomes, providing considerable information on the context of medical realities within which resuscitation should be placed. It is the purpose of this chapter to place a prospective decision not to resuscitate a patient in the legal context of a patient's right to choose treatment. As discussed below, this right may be exercised in many different forms, but is not without limits under the law.

The following discussion is in three parts, with relevant legal theories, judicial opinions, and statutory enactments included in each. The first places the issuance of a do-not-resuscitate (DNR) order firmly in the legal context of medical treatment decisionmaking. Also discussed are specific cases regarding the propriety of DNR orders, and information relating to special protection for elderly patients. Second, the structure of a DNR decision will be analyzed, focusing on the legal issues involved in assessing patients' wishes, empowering a surrogate when appropriate, and evaluating societal interests and judicial opinions on these issues. Finally, the report will briefly discuss legal consideration in the actual issuance and implementation of a DNR order.

I. Do-Not-Resuscitate Orders in Context of Medical Treatment Decisions for Elderly Patients

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A. DNR Orders in Context of Treatment Decisions

There is a paucity of reported decisions addressing the circumstances in which DNR orders are appropriate, and the ways in which such decisions may be made. This may be due to the fact that DNR decisions often have been made quietly and informally. However, as other chapters of this project discuss, a prospective decision not to resuscitate a patient in the event of cardiac arrest -- that is, a decision to classify a patient "DNR" or "no code" -- is often perceived as qualitatively different from a decision to forego other types of life-sustaining therapy.

The tremendous advances made in the medical capability to restore cardiac and respiratory functions have influenced practice to the extent that the assumption is that an arresting patient will be resuscitated. A DNR order directs caregivers not to initiate life-sustaining treatment and, thus, countermands the traditional course of behavior in the event of cardiac arrest; many persons may, therefore, view a decision to classify a patient DNR somewhat differently from a decision to withdraw a patient from a respirator.

Moreover, because the impetus for administering CPR is a particular and sudden event -- i.e., a cardiac or respiratory arrest -- the decision to perform CPR on an arresting patient is frequently made on a spur-of-the-moment, ad hoc basis. In contrast, in cases involving decisions regarding whether to forego other forms of life-sustaining treatment, the persons involved in the decision-making process generally have time to reflect and to weigh conflicting interests, and then arrive at a decision. While advance decisionmaking regarding withdrawing or withholding most forms of life-sustaining treatment thus may not appear to be critical, it is, in fact, essential in the context of deciding whether to initiate resuscitation.

It is, therefore, easy to understand that from an emotional standpoint, a DNR decision may seem to be different from a decision to forego other kinds of life-sustaining treatment. However, the analytical framework that must be used to evaluate the appropriateness of a DNR decision, and to direct the manner in which that decision should be made, is the same framework that is traditionally applied to assess other medical treatment decisions. Cardiopulmonary resuscitation, the administration of food or fluids by means of nasogastric tubes, and the injection of various types of drugs, all constitute external forms of medical intervention that prevent nature from running its course. All are "instituted by skilled health care providers to compensate for impaired physical functioning," and all attempt to "prolong life when the body is no longer able to perform a vital bodily function on its own." Matter of Conroy, 98 N.J. 321, 486 A.2d 1209 (1985). 000153

The starting point for analysis is the well-established principle that although there is a general presumption favoring necessary medical treatment, patients have the right to refuse such treatment. This right derives from the fundamental common-law and constitutional principles that protect individuals' liberty, bodily integrity, privacy and freedom of choice. Many professional associations have relied on these principles to develop policies, guidelines, and codes of ethics discussing patients' right to choose treatment based upon patients' right to self-determination. See, e.g., Joint Commission on Accreditation of Hospitals and American Hospital Association Policy and Statement "The Patient's Choice of Treatment Options;" both are quoted on page 11. Various state statutes and uniform laws now codify these common-law and constitutional principles as they specifically delineate the ways in which patients may exercise these rights. See, e.g., Massachusetts, Minnesota.

Competent patients may exercise their right to choose appropriate medical treatment by making their wishes known to attending physicians. If patients are incompetent, their rights may be exercised by surrogate decision-makers who may be identified either informally from among those persons with a natural relationship to the patient, or formally through judicial appointment of a guardian. These surrogates must attempt to ascertain patients' wishes regarding withdrawing or withholding life sustaining treatment, and use their "substituted judgment" in order to decide the course of treatment. The doctrine of substituted judgment is based on the theory that surrogates may make decisions on patients' behalf that will reflect the patients' reliably-evidenced views. If there is no guidance available for a surrogate regarding a patient's wishes, the decision must be based on what would be in the patient's best interest, evaluating such considerations as level of pain and suffering, and possibility of regaining self-determination.

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Many courts have articulated four "state interests" that are balanced against a patient's wishes in order to decide whether the patient's wishes can be carried out. Although courts identify states' interests in preserving life, protecting innocent third parties, preventing suicide, and maintaining the integrity of the medical profession, patients' wishes generally prevail and dictate the ensuing medical treatment decisions. Accordingly, once it is established that a patient does not desire life-sustaining treatment, it is usually possible for the patient's caregivers to honor those wishes.

While the analytical framework described above has been applied to many cases involving withdrawing or withholding respirators, intravenous transmission of food and fluids, blood transfusions, chemotherapy, and other similar procedures, it has been applied in few significant cases involving the appropriateness of prospectively classifying a patient DNR.

In In re Matter of Dinnerstein, 380 N.E.2d 134 (Mass. 1978), the court was reviewing the matter of a 67-year-old patient suffering from Alzheimer's disease and a variety of other disorders which, in combination, caused her to be confined to a hospital bed in an "essentially vegetative state." Mrs. Dinnerstein's attending physician told her family that her life expectancy was no more than one year, and recommended that if cardiac or respiratory arrest occurred, resuscitation efforts should not be undertaken.

The court implicitly acknowledged that incompetent patients have the right to choose to decline medical treatment, and agreed that it was appropriate for the family and physician of an incompetent patient to exercise this right on behalf of the patient. Finding no direct evidence of what Mrs. Dinnerstein would have desired under the circumstances, the court noted that life-sustaining treatment is in the best interests of a patient such as Mrs. Dinnerstein only when such

"treatments [are] administered for the purpose, and with some reasonable expectation, of effecting a permanent or temporary cure or relief from the illness or condition being treated."

Id. at 139. As a result, the court found that the decision to classify Mrs. Dinnerstein as DNR presented "a question peculiarly within the competence of the medical profession of what measures are appropriate to ease the imminent passing of an irreversibly, terminally ill patient in

light of the patient's history and condition and the wishes of her family." Id. Accordingly, the court approved the decision of the family and physician to classify Mrs. Dinnerstein DNR and stated that, in such a case, prior judicial review was neither necessary nor appropriate. 000156

In Custody of a Minor, 434 N.E. 2d 601 (Mass. 1982), however, the court outlined a slightly different approach to a prospective DNR decision, to be used in situations where the absence of "loving and caring [family] actively involved in medical decisionmaking" requires greater judicial participation. Id. at 610. The case involved "Baby Billy," an infant whose combination of irreversible heart condition led his physicians to conclude that he would not live past his first birthday. Because his mother had abandoned him at birth, Baby Billy was a ward of the state under the protection of the Massachusetts Department of Social Services. In response to a request by the hospital at which Baby Billy was being treated, the Juvenile Court entered a "no-code" order providing that if the child were to go into cardiac or respiratory arrest, no heroic resuscitative efforts would be undertaken. The court found that the child had an underlying terminal cardiac condition; and that resuscitative efforts would be invasive, traumatic, painful and could result in a further weakening of his condition and in possible neurological and kidney damage.

After the no-code order was entered, the hospital asked the Juvenile Court to revoke the order due to an improvement in the child's condition. Although all parties agreed that the order should be revoked, the Juvenile Court declined to revoke it, noting that although the child's immediate condition had improved somewhat, resuscitation would be inappropriate because his underlying incurable condition had not changed.

On appeal, the Massachusetts Supreme Judicial Court held that the Juvenile Court had acted appropriately in refusing to revoke the no-code

order, despite the fact that all interested parties -- the hospital, the Department of Social Services and the child's court-appointed guardian ad litem -- sought revocation of the order. The court disagreed with the parties' contention that because they all agreed to revocation of the order, the court had no further role to play. In this context, the court specifically distinguished Dinnerstein by noting that in that case, Mrs. Dinnerstein was not a ward of the state; rather, she had a son and daughter who, in consultation with her attending physician, agreed to a particular course of medical treatment, thus minimizing the need for judicial involvement. The court stressed that judicial intervention was especially appropriate in light of the child's irreversible medical condition and the absence of family members to act as surrogate decisionmakers; the court noted that under such circumstances the propriety of a no-code order is "best resolved by requiring a judicial determination in accordance with the instituted judgment doctrine."

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Very few other cases have dealt specifically with the issuance of a DNR order. Another case of note, Hoyt v. St. Mary's Rehabilitation Center focused on the appointment of an appropriate decisionmaker rather than on the propriety of the order itself.

C. Unique Vulnerability of the Elderly

Questions concerning the appropriateness of medical intervention in general, and cardiopulmonary resuscitation in particular, are clearly not limited to elderly patients. However, these issues frequently tend to arise with elderly patients, given the often problematic and complex nature of their medical conditions. The purpose of this section, specifically acknowledging the relationship of the elderly population to the primary topic, is simply to outline the various differences in

institutions in which such decisions are made and the special protection afforded by some jurisdictions.

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There may be certain special problems that some elderly patients may face in their conditions or environments. Many elderly patients who reach the stage at which questions regarding withholding or withdrawing life-support systems are raised reside in nursing homes. Although, as a legal matter, nursing home residents have the same rights as hospital patients, nursing home residents are nevertheless a "particularly vulnerable population" (Conroy). They are often quite elderly, and may fall into a general category of "frail elderly." In addition, nursing home patients often do not have caring and involved family members who can participate in decisions regarding medical care. Also, nursing homes have administrations, facilities, and environments that are different from hospitals, varying widely in organization and purpose regarding the level of medical care provided.

Certain jurisdictions have identified a need for special protection of elderly patients when it comes to making and/or implementing medical treatment decisions. The state of New Jersey, for example, has recognized this need by enacting a number of statutes imposing certain minimal requirements on providers of nursing home care, delineating certain rights held by nursing home patients, and establishing an "Office of the Ombudsman for the Institutionalized Elderly" to safeguard elderly institutionalized patients against a variety of forms of physical and mental abuse. See, e.g., N.J.S.A. §§ 30:13-1 through 11; §§ 52:27G et seq. These sections "create a vehicle for safeguarding the rights of elderly, institutionalized, incompetent patients both to receive medical treatment and to refuse life-sustaining medical treatment under certain circumstances." Conroy. Other examples of special protections, albeit

not exclusive to health care, are found in state statutes which protect against abuse of the elderly. See, e.g., Florida.

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II. Assessment of a Decision to Issue a DNR Order

The previous section of this chapter places the decision not to resuscitate within the broader context of decisions regarding medical treatment, especially those involving the withholding or withdrawal of life-sustaining treatment. The following discussion will outline the structure of a DNR decision from that standpoint, focusing on a legal assessment of the issues.

A. The Threshold Inquiry: The Patient's Medical Condition

The starting point for this discussion is an explanation of brain death since the term is often misunderstood, especially in this context. When there is irreversible cessation of all functions of the brain, including the brain stem, a person is dead, regardless of whether other bodily functions are being sustained by artificial means. Because a patient with "brain death" is dead, such a patient raises no issues about the appropriateness of withdrawing or withholding medical treatment. Most states have accepted a definition of brain death, either through statutory enactment or judicial interpretation.

Given that the fundamental right of patient self-determination is the cornerstone for the right to refuse medical treatment and thus forms the basis for a DNR decision, it would seem reasonable to assume that physicians could honor patients' desire not to be resuscitated in the event of cardiac or respiratory arrest, regardless of the patients' medical conditions. However, a patient is not typically considered to be eligible for a DNR classification unless the patient is "terminally ill,"

is suffering from an "irreversible" condition, or is facing an "expected" and "imminent" death.

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While these terms are subject to varying definitions depending upon a patient's individual circumstances, they do have one element in common. All of the patients described by these labels will certainly die of their underlying injuries or diseases within a relatively short period, whether or not they receive life-sustaining medical treatment. Many variations in a patient's medical status may be considered to fall under these definitions. For instance, the patient may be comatose or unconscious (e.g., Quinlan, etc.) or may be in a "chronic" or "persistent vegetative state," which indicates only minimal ability to respond to the environment and a very low level of brain function (e.g., Dinnerstein, Leach, etc.). In another case, a profoundly retarded patient with little or no ability to understand his environment may also suffer from an irreversible physical ailment such as cancer (i.e., Storar, Saikewicz). There also may be patients who suffer from a multiplicity of medical problems for whom cardiac or respiratory arrests would likely trigger the massive breakdown of physical systems ("multi-system organ failure") indicative of irreversible and, ultimately, fatal medical conditions.

What each of these patients has in common, and what may make appropriate the writing of a DNR order or foregoing other forms of life-sustaining treatment, is that the proposed medical intervention offers only the chance for a brief delay in the time of death.

B. Paramount Consideration: The Patient's Wishes

When a patient's medical condition has been deemed to be such that it may be appropriate to consider issuing a DNR order, the primary inquiry becomes whether there are current and/or previous expressions, either written or oral, as to the patient's desire to have life prolonged by artificial technology or procedures. This inquiry is mandated by the

fundamental right of patient self-determination that emanates both from the common law right to be free from nonconsensual invasion of bodily integrity, and from the unwritten constitutional right of privacy found in the "penumbra" of specific guarantees in the Bill of Rights. 000161

1. Fundamental Rights: Common Law and Constitutional

Regardless of a patient's mental status, an analysis of the patient's rights begins with a determination of the rights possessed by a competent patient to accept or reject medical care. This determination will apply to any patient, since the rights possessed by a competent person are possessed equally by an incompetent person who will simply need a third party to actually exercise these rights on his behalf. Accordingly, it is well-established that all persons have the right to control their own bodies and that the doctrine of informed consent is the primary means by which this right is protected. This doctrine presupposes that patients have at their disposal all the information necessary to evaluate the benefits and risks of proposed courses of treatment, and subsumes within it the ability to reject, as well as accept, particular types of medical intervention.

In addition to this common law right of self-determination, the right to make decisions about one's body is protected by the federal constitutional right of privacy first articulated in Griswold v. Connecticut, 381 U.S. 479 (1965), extended in Roe v. Wade, 410 U.S. 113 (1973), and applied in In the Matter of Quinlan, supra, to "encompass a patient's decision to decline medical treatment under certain circumstances," even if that decision might lead to the patient's death. Quinlan, Conroy.

2. Professional Ethics

From these common law and constitutional law principles, various professional associations involved in the provision of health care have developed policies and guidelines outlining a patient's right to control

the course of his medical treatment. For instance, the JCAH standards for hospital accreditation provide the "the patient may refuse treatment to the extent permitted by law." A recently published Policy and Statement: 000162
The Patient's Choice of Treatment Options from the American Hospital

Association states:

Whenever possible . . . the authority to determine the course of treatment, if any, should rest with the patient, who may choose to delegate it. In the hospital setting, institutional methods should be established to reasonably assure that the patient may exercise this authority on the basis of relevant information necessary to make a sufficiently voluntary and informed decision.

These standards were elevated almost to the level of legislative pronouncements in one case (cite) as the court struggled to define the extent of a patient's right to refuse life-sustaining medical treatment.

3. Statutory Protections

Many states now have statutes, called "Living Will Acts" or "Natural Death Acts," which specifically delineate these common law and constitutional rights. For instance, the California Natural Death Act (Cal. Health & Safety Code §7185 et seq.) provides that

adult persons have the fundamental right to control the decisions relating to the rendering of their own medical care, including the decision to have life-sustaining procedures withheld or withdrawn in instances of a terminal condition.

A "living will" statute empowers persons to sign "living wills," in which they may direct that if at any time they are suffering from medical conditions from which there is no reasonable expectation of recovery, they be allowed to die and not be kept alive by medications, artificial life-support systems, or "heroic" measures such as cardiopulmonary resuscitation. A "natural death" act expands this right to include directions based on properly witnessed oral statements by patients.

C. Surrogate Decisionmaking For Incompetent Patients

The more problematic cases involve incompetent patients who are incapable of making known their wishes regarding being sustained by artificial means, and who had not made a legally enforceable prior expression of those wishes. In such cases, the decisionmaking process becomes more complex, because once the patient's right to self-determination is established, a surrogate decisionmaker must be identified to exercise the patient's rights.

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Since judicial involvement in the process of deciding whether patients may forego life-sustaining medical treatment generally should be avoided, surrogate decisionmakers can be identified informally, from among those persons who have natural or close relationships with the patients. For instance, in the Quinlan case, the court envisioned that an incompetent patient's family, in conjunction with physicians and other involved parties, would be capable of exercising the patient's right to refuse medical treatment, without prior judicial approval either of the surrogate or of the substantive decision made. Similarly, in Barber v. Superior Court, 195 Cal. Rptr. 484 (1983), the court held that two physicians who, at the request of an incompetent patient's family, removed the intravenous tubes providing nourishment and hydration to the patient, would not be criminally liable for murder or conspiracy to commit murder. The Barber court implicitly acknowledged the legitimacy of the informal agreement between the patient's family and physicians to terminate life-support, and explicitly noted that judicial appointment of a guardian to exercise the patient's rights, while permissible, was not required. Id. at 492. See also, Dinnerstein.

In this context, hospital ethics committees can play a critical role. By providing a forum for open and honest discussion of complex

medical, moral and ethical questions by all concerned parties, they can facilitate resolution of difficult questions regarding appropriate medical treatment. In addition, physicians who have the benefit of advisory recommendations from a hospital ethics committee may feel more comfortable in complying with patients' wishes regarding their medical treatment, unless the physicians act in disregard of generally accepted medical standards. Courts have often spoken approvingly of discussion with ethics committees in this context. See Quinlan, Torres.

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If necessary, surrogate decisionmakers can be judicially appointed via guardianship proceedings comporting with the relevant provisions of state law. Courts are often faced with guardianship proceedings in cases of elderly incompetent patients. Indeed, in most cases involving the possible termination of life support for incompetent patients, the families, physicians and hospital may feel more comfortable with judicial involvement in their decisions, possibly at the level of guardianship proceedings. See, e.g., Conroy, Spring, Leach, Eichner, Storar, Saikewicz, Colyer. In most guardianship proceedings, the court will appoint a guardian ad litem who serves only during the pendency of the guardianship proceeding to represent the interests of the incompetent patient. In this manner, the court can ensure that the proposed guardian's interests are completely consistent with those of the incompetent patient, and that the proposed guardian is, in fact, the person most qualified to exercise the patient's rights.

In addition, in states which provide for the execution of a durable power of attorney, patient may, while still competent, choose the person or persons whom they would like to exercise their rights, including the right to refuse medical treatment, if they should become incompetent. See Bartling v. Superior Court; California Durable Power of Attorney for Health Care Act, Cal. Civil Code §§ 2430-2443.

Once appropriate surrogates have been identified, they face the difficult task of actually exercising patients' rights. Although the language in reported cases is somewhat unclear, most courts appear to agree that surrogates should be guided in their decisions first by their knowledge of the patients' own desires and feelings, to the extent that they have been competently expressed. If, and only if, it is not possible to ascertain the choice the patients would have made, then the surrogates should make their decisions based upon the patients' best interests.

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Surrogates, therefore, must look first to any prior expressions made by incompetent patients that would in any way bear on the question of whether the patients, were they competent, would choose to withdraw or withhold life-sustaining treatments. For example, in Eichner, the court that allowed the discontinuation of a respirator for Brother Fox, a Catholic brother, seemed swayed by the consistent way in which Brother Fox, while competent, had expressed his views on artificial life-support and his fervent desire that he not be sustained by those means. Indeed, only months before undergoing the operation that rendered him incompetent, Brother Fox had repeated several statements that he had made earlier, that he would not want his life prolonged by such means if his condition were hopeless. Eichner. See also, Leach v. Akron General Medical Center, 68 Ohio Misc. 1, 426 N.E.2d 809, 811 (1980). The weight which surrogates, or courts reviewing surrogates' decisions, will give to patients' prior expressions will vary depending on an assessment of their probative value. See, e.g., Quinlan (the court found that, given her youth and the casual nature of her conversations, Karen Quinlan's statements to friends to the effect that she would not want to be kept alive on life-sustaining machinery had little probative value as to what, in fact, she would have desired).

In attempting to ascertain incompetent patients' wishes, surrogates may also consider indirect evidence bearing upon the patients' desire to refuse life-sustaining treatment. For instance, in In the Matter of Colyer, 99 Wash. 2d 114, 660 P. 2d 738, 748 (1983), the court accepted as the basis for a decision to discontinue life-support systems the guardian's conclusion that the patient "was a very independent woman, that she disliked going to doctors, and that, if able to express her views, she would have requested the treatment be withdrawn."

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This "subjective" approach according to which "the question is not what a reasonable or average person would have chosen to do under the circumstances, but what the particular patient would have done if able to choose for himself" (Conroy) appears to be the preferred method of surrogate decisionmaking. As the court in Conroy noted, a patient's wishes may be ascertained from a living will or durable power of attorney, an oral directive to a family member or friend, the patient's religious beliefs and the tenets of that religion, or from the "patient's consistent pattern of behavior with respect to prior decisions about his own medical care," as well as any other relevant information. Conroy.

If there is no evidence, however, as to what patients would have wanted, then surrogate decisionmakers must decide what would be in the patients' best interests. Saikewicz, etc. This assessment seems to assume an "objective" viewpoint not far removed from a "reasonable person" inquiry, which asks what a reasonable person would consider to be in his best interests. In fact "the primary test is [still] subjective in nature -- that is, the goal is to determine with as much accuracy as possible the wants and needs of the individual involved." Saikewicz at 430. Despite the different ways in which surrogates' responsibility to act according to incompetent patients' "best interests" may be outlined, it is fairly clear

that in carrying out this mandate, surrogates should consider "such factors as the relief of suffering, the preservation or restoration of functioning, and the quality, as well as the extent, of life sustained."

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Colyer at 493. In Deciding to Forego Life-Sustaining Treatment, the President's Commission stated:

In assessing whether a procedure or course of treatment would be in a patient's best interests, the surrogate must take into account such factors as the relief of suffering, the preservation or restoration of functioning, and the quality as well as the extent of life sustained. An accurate assessment will encompass consideration of the satisfaction of present desires, the opportunities for future satisfactions, and the possibility of developing or regaining the capacity for self-determination.

However, as the Conroy court noted, most courts "expressly decline to authorize decisionmaking based on assessments of the personal worth or social utility of another's life, or the value of that life to others."

Conroy.

D. State Interests

Although courts have accepted patients' right to self-determination and have outlined the means by which this right may be exercised by patients or surrogates to authorize the withdrawal or withholding of life-sustaining medical treatment, this right is not absolute. The courts have identified four arguably countervailing state interests that must be balanced against the patients' right of self-determination. Even though these interests are mentioned in virtually every case in which issues regarding foregoing life-sustaining treatment are raised, most courts recognize that, in fact, states generally do not have any interests that are implicated by decisions among physicians, patients and family members regarding an individual's choice of medical treatment. As a result, although most courts discuss the four state interests that will be briefly described below, patients' rights generally are deemed to supersede these proffered state interests.

The preservation of life, the most significant state interest, is considerably weakened where continued treatment serves at best to prolong a life inflicted with an incurable condition. See, e.g., Quinlan, Colyer. On the other hand, the state's interest in preserving life was probably the basis for the court's conclusion in In the Matter of Storar, supra, that the mother and guardian of a profoundly retarded cancer patient could not request the discontinuation of the blood transfusions which, even though they would not cure the cancer, would eliminate the risk of death from another treatable cause. Similarly, in Saikewicz, the court may have felt that the chemotherapy treatments in question could possibly have brought about a remission of the patient's cancer, even though they could not cure the underlying disease. The "irreversibility" or "hopelessness" of the patient's condition, added to a consideration of a treatment which would prolong death rather than life, albeit difficult to define, appear to be key elements in assessing the interest in preservation of life.

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A second state interest is that of protecting third parties, particularly minor children, from the "emotional and financial damage which may occur as a result of the decision of a competent adult to refuse life-saving or life-prolonging treatment." Saikewicz at 426. While significant, this interest has never been held to supersede a patient's choice to refuse such treatment, for the likely reason that it is not usually a factor in most of the cases in question. The cases here dealt largely with either an incompetent patient whose decision is not likely to have an emotional or financial impact upon others, or with elderly patients, who are seldom in the position of leaving behind minor children or others who could be cared for more adequately if the proposed treatment were rendered.

The state also has an interest in preventing suicide, but that interest has received little discussion in these cases in view of the fact that "a death which occurs after the removal of life-sustaining systems is from natural causes, neither set in motion nor intended by the patient," and therefore is not suicide. Colyer at 743. However, the weight given to this interest will be profoundly affected if the patient's condition is one which puts the "terminal" or "irreversible" status of the patient in question. See, e.g., Bouvia. 000169

Finally, the state is concerned with maintaining the ethical integrity of the medical profession. However, this concern is never more important than the patient's rights in the context of a terminal patient. The courts will focus on whether a particular treatment plan is likely to offer a reasonable hope of benefit to a patient and will not impose undue burdens. If the court concludes that such benefit exists, then the proposed treatment should be provided. If, on the other hand, the court concludes that no such benefit exists, then the proposed treatment plan need not be provided. The Saikewicz court's discussion of this issue is particularly articulate:

[p]revailing medical ethical practice does not, without exception, demand that all efforts toward life prolongation be made in all circumstances. Rather, as indicated in Quinlan, the prevailing ethical practice seems to be to recognize that the dying are more often in need of comfort than treatment. Recognition of the right to refuse necessary treatment in appropriate circumstances is consistent with existing medical mores; such a doctrine does not threaten either the integrity of the medical profession, the proper role of hospitals in caring for such patients or the State's interest in protecting the same. It is not necessary to deny a right of self-determination to a patient in order to recognize the interests of doctors, hospitals, and medical personnel in attendance on the patient. Also, if the doctrines of informed consent and right of privacy have as their foundations the right to bodily integrity, see Union Pac. Ry. v. Botsford, 141 U.S. 250, 11 S.Ct. 1000, 35 L.Ed. 734 (1891), and control of one's own fate, then those rights are superior to the institutional considerations.

E. Judicial Involvement in Medical Treatment Decisions

Even those health care professionals who confront issues of life and death on a daily basis, and even concerned, caring family members who sincerely want what is best for a dying relative, are frequently unable to decide whether and under what circumstances it is appropriate to withdraw or withhold from a particular patient life-sustaining treatment, including cardiopulmonary resuscitation in the event of a cardiac arrest. As a result, although most medical treatment decisions are made by physicians, patients and families without judicial involvement, courts are, nonetheless, frequently asked to intervene. 000170

Virtually every court that has considered whether a patient may forego life-sustaining treatment has attempted both to formulate substantive guidelines for decisionmaking, and to articulate the procedures that should be followed in making these decisions. See, e.g., Conroy. As discussed above, courts acknowledge the fundamental right of patient self-determination, and attempt to reconcile it with any applicable countervailing state interests, in an effort to ascertain whether a proposed course of medical treatment offers a reasonable hope of benefit that will outweigh the burden to the patient.

During the past decade, the courts that have been presented with these questions have differed in their assessment of the need for judicial involvement. These courts have reached different conclusions regarding the appropriate level of judicial involvement in making medical treatment decisions. In Matter of Quinlan, 355 A.2d 647 (N.J. 1976), for instance, the court stated that

"a practice of applying to a court to confirm such decisions would generally be inappropriate, not only because that would be a gratuitous encroachment upon the medical profession's field of competence, but because it would be impossibly cumbersome . . . decision-making within health care if it is

considered as an expression of a primary obligation of the physician, primum non nocere, should be controlled primarily within the patient/doctor/ family relationship . . ."

Id. at 669. Accord. On the other hand, in Superintendent of Belchertown

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State School v. Saikewicz, 370 N.E.2d 417, 434-5 (1977), the court took a

dim view of any attempt to shift the ultimate decisionmaking responsibility away from the duly established courts of proper jurisdiction to any committee, panel or group, ad hoc or permanent . . . we do not view the judicial resolution of this most difficult and awesome question -- whether potentially life-prolonging treatment should be withheld from a person incapable of making his own decision -- as constituting a "gratuitous encroachment" or the domain of medical expertise. Rather, such questions of life and death seem to us to require the process of detached but passionate investigation and decision that forms the ideal on which the judicial branch of government was created. Achieving this ideal is our responsibility and that of the lower court, and is not to be entrusted to any other group purporting to represent the "morality and conscience of our society," no matter how highly motivated or impressively constituted.

Accord, Spring, etc.

The degree to which courts have thus far involved themselves in the type of decisionmaking at issue here seems to depend on the specific facts of the individual case before them, and particularly upon their assessment of the degree to which the patient's rights can be protected by family and physicians without the need for judicial supervision or oversight. For instance, the patient in the Saikewicz case was a 62-year-old man, suffering from acute myeloblastic monocytic leukemia, who had been profoundly retarded since birth, and who had lived in state mental institutions for 50 years. Because he had no family who chose to be involved in his medical care, and because he was completely incapable of understanding his medical needs or making any decisions regarding his own health care, the state of Massachusetts was completely responsible for his welfare. Under these circumstances, it is hardly surprising that the Saikewicz court felt compelled to outline a clear role for the judiciary in order to make sure that Mr. Saikewicz' needs and interests were fully accounted for.

On the other hand, the Quinlan case, in which the court approved a much more limited judicial role, was replete with references to the close 000172 and loving relationship between Karen Quinlan and her father, who was seeking permission to be appointed her guardian, to the excellent medical and nursing care she was receiving, to the availability of an institutional "ethics committee" at a private, religiously affiliated hospital, and to the involvement of the clergy. The Quinlan court apparently believed that under these circumstances Karen Quinlan's interests could be adequately safeguarded without judicial involvement. A similar conclusion was reached, albeit in a vastly dissimilar factual situation and judicial decision, in Bartling v. Superior Court, 209 Cal. Rptr. 220 (1984), in which the court, faced with a competent patient whose desire not to be sustained via artificial means had been recorded several times in both oral and written form, stated that physicians and patients confronting similar situations in the future "should be free to act according to the patient's instruction without fear of liability and without advance court approval." Id. at 226.

It must be emphasized, however, that prior judicial review of medical treatment decisions is not required. It is true, of course, that only a prior judicial review of a medical treatment decision can provide the hospital and the treating physicians with an absolute grant of immunity from liability in connection with the implementation of that decision. However, no court would suggest that every such case must be presented to a court for advance review.

Quite clearly, then, although courts have expressed varying degrees of willingness to hear such cases when they are presented to them, and although judicial involvement may be completely appropriate when the relevant parties disagree as to a particular medical treatment decision,

no court has required that any advance judicial review take place in these cases. And, indeed, the vast majority of decisions to forego life-sustaining treatment are, quite properly, made without any judicial involvement whatever. 000173

III. The Issuance and Implementation of a DNR order

This analysis suggests that a DNR decision should be made in precisely the same way as any other decision regarding withholding or withdrawing life-sustaining medical treatment. Given the desirability for advance decision-making in an institutional setting, however, it is important that a mechanism be established to deal with individual cases as they arise. In light of the sudden and unexpected nature of cardiac or respiratory arrest, resort to ad hoc decisionmaking in this arena could nullify the irreversibly ill patient's right to determine the way in which he will live out his remaining days or months, and the manner in which he will ultimately die. In addition, such decisionmaking can undermine the protections that physicians and other caregivers would have if they were making medical treatment decisions according to clearing defined policies.

This discussion will be necessarily brief in light of the critical variations in hospital services, mission and physicians. It would be inappropriate to set forth strict guidelines regarding DNR policy.

It may be advisable for an institution to have a written policy on DNR orders, and would certainly be an advantageous, thoughtful exercise for an ethics committee or other group within the hospital to go through the process of discussion and resolution regarding the issues. At a minimum the policy should consider when and how an order is to be entered on a patient's chart following discussion between physician and patient or surrogate and agreement on propriety of such an order.

VII Conclusions, Recommendations, and Evaluation of the Potential for Standardized Guidelines

As stated in the original proposal for the OTA project on Assessment of Life-Sustaining Technologies in the Elderly "Recent technological advances in the treatment of chronic disease and acute illness, combined with greater access to such care, make it possible to keep persons alive who might never have survived in the past." This is the reason why Congress finds itself interested in the questions of life-sustaining technologies for the elderly in general and the specific issue of cardiopulmonary resuscitation in the elderly. Because of Medicare reimbursement for health care for Americans who are over the age of 65, and because of the steeply increasing costs of that health care, Congress finds itself asking the question of whether there are expensive technologies being used which are ineffective and which therefore could be avoided. In the case of cardiopulmonary resuscitation data is currently inadequate to make systematic recommendations about withholding this treatment, but explicit policies for decision making can be endorsed.

We have reviewed all of the current literature on the subject of cardiopulmonary resuscitation in the elderly as follows:

- I. The technology of resuscitation was developed primarily in the 1960's with the advent of electrical cardiac monitoring, defibrillation, and concomitant understanding of the role of medications in stabilizing cardiac arrhythmias. While attempts have been made to improve the techniques and technology of cardiopulmonary resuscitation in the intervening decades there has not in fact been another quantum leap since that time in our ability to resuscitate people. It appears that external cardiac massage and the basic stimulant and stabilizing drugs remain the state-of-the-art. No distinct improvement has been achieved by either mechanical devices for cardiac massage, mechanical devices for redistributing blood flow, open cardiac massage, or newer pharmacological preparations. Research will continue in this area, but most experts in the field agree that the most important variable in improving outcomes from cardiopulmonary resuscitation is in the immediate identification of cardiac and respiratory arrest and the rapidity of the intervention. For this reason there was a great deal of excitement in the 1970's in extending knowledge of the techniques of cardiopulmonary resuscitation into the community. The most well known, the Seattle, Washington area, trained people in schools and community groups to do cardiopulmonary resuscitation, so that if someone collapsed on the street anyone could rapidly intervene. Currently there is substantial skepticism about whether the good results of the Seattle area could be reproduced in other areas and programs of that scope have not been duplicated. The ability to do cardiopulmonary resuscitation is a substantial life saving technology. It has been demonstrated that CPR can be extended outside of the acute care hospital and the emergency room into the community, and, into nursing homes as well.
- II. The pattern of utilization of cardiopulmonary resuscitation in the elderly varies widely from institution to institution and has probably been changing over the past 15 years. Hospitals have become more willing to forego resuscitation in some patients either by their request or because of their poor medical condition, and bad prognosis. Because cardiopulmonary resuscitation can occur anywhere in the hospital and is not coded as a surgical procedure it is difficult to obtain accurate figures for either local or national utilization of CPR. Approximate figures, however can be derived. Approximately 75,000 community and 245,000 hospital

arrests occur each year in the United States. Hospital resuscitation occurs in 1 to 2% of all admissions, and can produce approximately a 6% reduction in hospital mortality. Comparable figures for long term care facilities are not currently available. The success rate for cardiopulmonary resuscitation in general, is approximately 35% in the community and as high as 50% in hospital resuscitation, in which 15% of those patients resuscitated survived to hospital discharge and are alive a year later. The majority of cardiac arrests are due to coronary artery disease and the most common rhythm disturbance is ventricular fibrillation. Ventricular fibrillation is also the most easily reversed of the arrhythmias causing cardiac arrest. A substantial portion of patients surviving the initial cardiopulmonary resuscitation experience new neurologic injury but the extent of permanent neurological deficits is difficult to ascertain. Survivors of resuscitation do require increased medical resources usually involving intensive care unit admission for at least a day and sometime longer. The paucity of available data suggests a need for uniform reporting of this kind of data and a collection of more detailed information on utilization and outcomes before specific policy on CPR in the elderly should be formulated. Nursing homes for example need to be more carefully studied in the feasibility of more effective cardiopulmonary resuscitation being performed in those settings and more clear decisions being made about the patients in whom it should be done.

- III. The cost of cardiopulmonary resuscitation is likewise difficult to ascertain, especially when one is outside of the hospital area. Using the number of 245,000 hospital cardiac arrests in persons over 65 every year one could estimate the number of hospital resuscitations performed. If CPR is performed in the majority of those arrests and if the success rate is 50% and the cost per case approximately \$7,000 the total national annual cost of in hospital cardiopulmonary resuscitation in the elderly is approximately \$8,886,000. If 50% of them are successful then that is the cost of 123,000 lives saved, 18,000 of them surviving to hospital discharge and beyond.
- IV. Decisions not to resuscitate have been the subject of a great deal of controversy in health care institutions and in biomedical ethics in the past decade. In acute care hospitals the presumption has been to resuscitate any patient who has a cardiac arrest. This can be ethically justified by the need to respond rapidly at the time of a cardiac arrest. Therefore deliberation should occur in advance, and patients who are not to be resuscitated must be clearly identified. A problem is how that decision is to be made and to be transmitted to the health care team. Increasingly, it is thought that explicit communication of such a decision, and a notation in the patient's chart should all be included. Nursing homes have traditionally not had the capacity to do CPR. The institutions may be seen more as homes than as health care facilities. As sicker people are discharged to nursing homes from hospitals under the influence of DRG's, the issue of cardiopulmonary resuscitation in nursing homes is now arising. Where formerly as a patient became very ill it was usual to transfer that patient to the hospital, it is no longer always possible to do so. Nursing home administrators are feeling responsible for training their staff in the life saving interventions in critically ill older persons. This area in long term care is in a great deal of flux now and no surveys have been published which identify the numbers of long term care facilities that do perform CPR.

A number of studies have been done about the decision-making process in cardiopulmonary resuscitation, and they have found wide variation in that practice. It is unusual in any of the studies that age alone is a major factor in the decision not to resuscitate the person. Functional status or "quality of life"

considerations such as mental impairment, and bedfast condition, do seem to correlate with the decision not to resuscitate. The question is whether these conditions are the reason the physicians make the DNR decision or whether it is patients who have these characteristics who also have multiple medical conditions indicating a poor prognosis in a resuscitation attempt.

- V. Resuscitation policies are being developed in health care institutions throughout the country. While they vary widely from institution to institution they have in common the following characteristics:
1. a statement that resuscitation should be initiated unless there is an explicit order to the contrary;
 2. a statement regarding the patient's wishes about resuscitation;
 3. a statement of the medical conditions which should be present to justify a decision not to resuscitate;
 4. a statement regarding the role of family or friends;
 5. a statement regarding the implementation of DNR orders and the recording of them in the chart.
 6. a statement about the scope of the order, for example that a DNR order should not limit other forms of medical intervention.
 7. a statement regarding the obligation of various persons responsible for the care of the patient.
- VI. The legal context in which decisions about cardiopulmonary resuscitation in the elderly occurs is likewise in the process of evolution. There is substantial legal precedent for a requirement that competent patients be included in decisions about their own medical care. This extends likewise to decisions about cardiopulmonary resuscitation. Any patient has a right to refuse cardiopulmonary resuscitation as a treatment and competent patients should therefore be included in that decision. Studies showing that most physicians do not discuss it with patients indicates the difficulty of this kind of communication. The presumption in law as well as in ethics is to attempt resuscitation except when the outcome would be undeniably unsuccessful or when the patient refuses.

Recommendations:

Because of the dramatic ability of cardiopulmonary resuscitation to save lives, and because of the relatively simple interventions that it entails, health care institution must act under the presumption to resuscitate. Age alone should not be a criterion for withholding cardiopulmonary resuscitation from a human being. Poor medical prognosis or a competent patient's refusal are the only acceptable reasons for a decision not to resuscitate. Hospitals, nursing homes, and other institutions, are widely individual in how they handle these ethical decisions. That individuality should be preserved and their ability to develop their own methods of dealing with it should be promoted. National societies, associations, and state level agencies should support and assist in the development of institutional mechanisms for decisions about resuscitation but should not themselves promulgate guidelines to that end. The authors of this report strongly agree that information is insufficient at this time to make any recommendations about uniform

national guidelines for cardiopulmonary resuscitation in the elderly and that it would be an ethical and legal mistake to tie reimbursement policies to those decisions.

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October 15, 1985

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On 4/9/85, I received a request from the Congress of the United States, Office of Technology Assessment, to propose how comprehensive information could be obtained about prolonged mechanical ventilation in the U.S.A. This documentation was needed for a more global report due in Congress by Spring, 1986: Life Sustaining Technologies and the Elderly.

It was clear to me, and those with whom I network, that the anticipated time was near for public policy debate that would determine what system, if any, would be put in place to benefit the ventilator-assisted individual. For over 5 years, I and other members of Care for Life have been making efforts to increase awareness about care for life-supported persons. Therefore, it was with gratitude and humility that I accepted this challenge for all those contributors who made the commitment to meet it.

The enclosed document represents a very major initiative to create knowledge which never before existed. However, this has been exactly what Care for Life has done over and over again in its short five year history. It has been our hope that someday a workable system will be put in place for the person who requires life-supportive technology. We believe that such an individual represents complex medical and social issues; what is put in place can serve as a model for other complex challenges of modern living.

I am proud to offer the final report to the OTA with the hope that its content will help the OTA create a statement of truth. The wish of all contributors is for a properly informed public policy. We are all grateful to the OTA for this opportunity to serve.

Allen I. Goldberg, M.D.

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October 15, 1985

Care for Life is a national resource and international networking organization which endeavors to:

- 1) Improve the quality of life and reduce the cost for those persons with prolonged dependency on technical and nursing care by enabling life in the least possible restrictive environment which skillfully and safely serves their medical and developmental needs and restores whenever possible their family relationships.
- 2) Develop models for home care and other home-like alternatives to permanent institutionalization including the training of persons and families to accomplish this goal by helping themselves.
- 3) Encourage and accomplish needed research on all related issues.
- 4) Collect documentation of successful individual cases and programs from every available source throughout the world.
- 5) Assemble current data on all available equipment and other resources to assist in establishing operational programs.
- 6) Disseminate nationally and internationally all currently available information on programs, equipment, and all other available resources to assist:
 - A. Institutions in preparing patients for return to home.
 - B. Families in coping with a program of home care for persons with permanent disability.
 - C. Health care professionals and social agencies in bridging the gap for their disabled patients and clients from permanent institutional life to living in a home environment.
 - D. Federal, state, and local governments in establishing safe programs to accomplish a simultaneous savings of vast sums of money while improving the quality of life for these persons with permanent disability.
 - E. Concerned people in the insurance industry, business and labor communities, and the lay public in understanding the tremendous potential for radically reducing health care costs while providing for people with permanent disability to learn, live, and work outside an institution in order for those concerned to support this effort financially and as working volunteers and to prevail upon their governments to join and assist this economically necessary movement.
 - F. Privately-funded organizations and private-sector health care providers in establishing operational local or regional programs to accomplish these goals.

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SPECIAL ACKNOWLEDGEMENT

I want to express my gratitude to Frank L. Seleny, M.D., Head, Department of Anesthesiology, Children's Memorial Hospital, Chicago for his limitless faith in and encouragement of my work. I also appreciate the support given to me by the members of the Departments of Anesthesia and Pediatrics, and the Administration of Children's Memorial Hospital. Finally, I want to sincerely thank Pat Peano for her efforts to prepare this manuscript for OTA which were far beyond any call of duty.

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY

PROLONGED MECHANICAL VENTILATION

TASK 1. OUTLINE

October 15, 1985

Prepared By:

Allen I. Goldberg

LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

The following outline will identify the tasks assigned by the OTA and their major sections. The issues of concern to the OTA, and those who made contributions to their discussion, are shown. Please refer to each task for a table of contents and a description of the qualifications of the contributors.

Task 2. Description of Mechanical Ventilation and Its Application

A. Review development of the technology and its use

- 1) Historical perspective in the U.S.A. (Affeldt, Alba, Goldberg, Laurie)
- 2) Definition of key concepts (Goldberg)
- 3) Goals of ventilator care (Goldberg, Indihar)
- 4) Characterize range of patients-adult experience (Alba, Indihar)

B. Describe variety of modern equipment and settings used

- 1) How ventilators work (Goldberg, Indihar)
- 2) Alternative methods; comparison of available mechanical devices; indications and contraindications (Alba)
- 3) Patient-Machine Interface (Goldberg, Indihar)
- 4) Monitoring technology (Goldberg, Indihar)
- 5) Preferred technology for elderly (Alba, Goldberg, Indihar)
- 6) Complexity of equipment; feasibility of self-care, care by non-professionals (Alba, Goldberg, Indihar)

Task #2 was assigned to contributing authors as indicated. An attempt was made to invite an interdisciplinary group to be certain that it had included the perspectives of pulmonologists, rehabilitation specialists, intensivists, nursing, allied health personnel, and consumers. The task was also assigned to selected organizational leaders to be certain that it presented a balanced opinion.

Task 3. Data on Utilization and Cost: A Survey*

A. Prevalence data (by age)

- 1) Acute primary diagnoses
- 2) Secondary diagnoses and circumstances
- 3) Specific chronic illnesses

B. Incidence data

- 1) By age (under 65 and elderly subgroups)
- 2) By other major variables
- 3) By care settings and age

* Appendix includes tabulation of survey data and commentary from key informants, selected experts, and related organizations.

C. Prevalence/incidence data interpretation

- 1) Evidence of care-rationing based on age
- 2) Evidence of unmet needs, unjustified use of technology, inefficient use of settings (re: elderly)
- 3) Utilization trends (past, present, future); implication for home care (re: elderly)

D. Cost-reimbursement data from health care providers (re: care setting, duration of treatment)

- 1) Total treatments costs per patient (by age group)
- 2) Costs paid by patients (self-pay)
- 3) Public reimbursement (Medicare, Medicaide, Veteran's Administration)
- 4) Private sector reimbursement (private insurance, Blue Cross)
- 5) Other reimbursement (private agencies, foundations, self-insurance, HMO, etc).

E. Cost-reimbursement data interpretation

- 1) Evidence of insurance coverage or ability to pay as factor in obtaining care
- 2) Impact of reimbursement regulations on utilization and cost
- 3) Cost trends (past - present - future)

The time and budgetary constraints of this OTA project limited survey efforts to Task 3. The Center for Health Administration Studies, University of Chicago, was asked to coordinate a multi-contributor

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effort. Those responsible for the survey design, implementation, and analysis were:

Ronald Anderson, Lu Ann Aday, Marlene Aitken, Susen Dunmire (Center for Health Administration Studies - University of Chicago)

with the assistance of:

Candice Clark (Montclair State College, Montclair, NJ)

Bernard Goldstein (Dept. of Sociology, Rutgers University, New Brunswick, NJ)

Sam Giordono (American Association for Respiratory Therapy, Dallas, TX)

Howard Robboy (Trenton State College, Trenton, NJ)

Key informants (institutions, settings, organizations) and contacts surveyed included the following:

<u>Organization</u>	<u>Location</u>	<u>Contact</u>	<u>Settings</u>
Boston University	Boston, MA	Barry Make	Rehabilitation Nursing Home Home Care
Gaylord	Wallingford, CT	R. Ferranti S. Flores	" "
Goldwater Memorial Hospital	New York, NY	Augusta Alba Mathew Lee	" "
Chicago Lung Association	Chicago, IL	Donna Frownfelter Richard Hughes	Illinois survey to include acute care, nursing home, and home care

<u>Organization</u>	<u>Location</u>	<u>Contact</u>	<u>Settings</u>
Bethesda Lutheran Hospital	St. Paul, MN	Frank Indihar Donald Mills	Long Term Care Home Care
Institute for Research & Rehabilitation	Houston, TX	Mark Splaingard Guy Harrison	Rehabilitation Home Care
Ranchos Los Amigos	Downey, CA	William Prentice	Rehabilitation Long Term Care Home Care
Emory Clinic	Atlanta, GA	Alan Plummer	Acute Care Home Care
Creighton University	Omaha, NE	William O'Donohue	Acute Care Home Care
University of Wisconsin	Madison, WI	Rita Giovannoni	Acute Care Rehabilitation Home Care
St. Michael's Hospital	Toronto, Canada	Robert Byrick	Acute Care

Task 4. Outcomes of CareA. Medical outcomes (Alba, Byrick, Goldberg, Indihar)

- 1) Physiologic effects, prognosis, need for further care
- 2) Rates of survival, death, dependency on mechanical ventilation;
degree of dependency
- 3) Impact on functional ability (including mental competence)
- 4) Technology: safety and risk

8. Social, Psychological, Economic Outcomes (Pfrommer, Laurie, Goldberg, Byrick)

- 1) Input on quality of life (re: setting)
- 2) Impact on family (include: finances)
- 3) Impact on caregivers
- 4) Impact on dying process

Authors for Task 4 were responsible for their own opinions based upon their experiences as professionals, consumers, researchers and/or organizational leaders. They recruited and incorporated input of other experts including consumers to be certain that multiple perspectives were represented. Other invited commentary was sought to assure a balanced opinion.

Task 5. Factors Influencing Treatment Decisions

- 1) Who is the decision-maker?
- 2) What patient characteristics affect the decision?
- 3) What factors influence the change of care settings?
- 4) What is the role of age in decision-making?
- 5) What patient characteristics affect inappropriate attention?
- 6) How are patients evaluated? How do evaluations affect decisions?
- 7) Are decision-makers knowledgeable and open-minded about the issues?
- 8) How do institutional norms and guidelines affect decisions?
- 9) How do religious beliefs and cultural values influence treatment decisions?
- 10) What is the role of the persons themselves in decision-making?
- 11) How and to what extent does practice vary in different parts of the U.S.?

12) How existing legislation and legal precedents affect decisions?

13) What is the international experience?

All the above questions were assigned to the following expert authors who incorporated the input of nursing, respiratory care, hospital administration, and the consumer. Case scenarios were offered by some contributors to illustrate reality.

Augusta Alba
Robert Byrick
Donna Fronfelter
Allen Goldberg
Rita Giovannoni
Frank Indihar
Barry Make
Walter O'Donohue
Margaret Pfrommer
Alan Plummer
William Prentice
Geoffrey Spencer

Task 6. Conclusions & Implications

- 1) What is the importance and urgency of problems of the elderly re: mechanical ventilation?
- 2) To what extent are these issues specially significant to the elderly?
- 3) What issues can be settled by professional, community, or private-sectors?
- 4) What issues require congressional actions?
- 5) Are treatment guidelines necessary?

- 6) What issues are raised for research?
- 7) What are preventative means that could be implemented?
- 8) What issues should be priority for public attention?
- 9) What issues are amenable for public policy change?
- 10) What are the public policy options?

The above questions were assigned to the following expert authors who commented from their perspectives as well as from others they recruited to supplement their expertise.

Lu Ann Aday
Marlene Aitken
Susen Dunmire
Donna Frownfeldter
Sam Giordono
Bernard Goldstein
Frank Indihar
Ed Roberts

Due to the significance of the issues, and the need for expertise in public policy, this task was coordinated by Ed Roberts, internationally-respected leader of the independent living movement for the disabled and a person benefiting from prolonged mechanical ventilation for 3 decades. Ed Roberts, Founder, World Institute for Disability, has devoted his career to public policy issues as they impact the disabled; he understands well the common issues facing both disabled and elderly persons.

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LIFE-SUSTAINING TECHNOLOGIES AND THE ELDERLY

PROLONGED MECHANICAL VENTILATION

TASK 2. DESCRIPTION OF MECHANICAL VENTILATION AND ITS APPLICATION

October 15, 1985

Prepared By:

Augusta Alba

Allen I. Goldberg

Frank J. Indihar

Gini Laurie

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The historical background and description of mechanical ventilation and its application have been addressed by the following experts:

- Dr. Augusta Alba - Physiatriist/Neurologist. Authority on long-term respiratory care in the pioneering Howard A. Rusk Respiratory Rehabilitation Service, Goldwater Memorial Hospital, New York, NY.
- Dr. Frank Indihar - Practicing Internist/Pulmonologist. Innovator of long-term respiratory care unit at a large metropolitan medical center, Bethesda Lutheran Hospital, St. Paul, MN.
- Gini Laurie - Internationally-recognized authority on the history of long-term respiratory care. Editor, Rehabilitation Gazette; Founder, Gazette International Networking Institute, St. Louis, MO.

The final draft has been supplemented by commentary from invited experts:

- Dr. John E. Affeldt - Nationally-recognized leader in the organization and evaluation of health care delivery. Former Medical Director, Rancho Los Amigos Hospital; innovator of first polio center and home care program for ventilator-dependent individuals. Former Medical Director, Department of Public Health, County of Los Angeles. Currently, President, Joint Commission on Accreditation of Hospitals (JCAH).
- Dr. Barry Make - Pulmonologist. Director of Respiratory Care Center, University Hospital, Boston, MA. Former Medical Director, Medical ICU, Boston City Hospital, Boston, MA. National authority on the care for ventilator-assisted adults. Innovator of special center for rehabilitation of patients with chronic respiratory disorders.

LIFE-SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 2. DESCRIPTION OF MECHANICAL VENTILATION AND ITS APPLICATION

A. REVIEW DEVELOPMENT OF THE TECHNOLOGY AND ITS USE

1) Historical perspective in the U.S.A. (Alba, Affeldt, Goldberg, Laurie)

Prolonged mechanical ventilation began with the development of the modern iron lung in the 1920's; however, technology progressed most rapidly during the polio experiences of the 1950's.* The first lung was devised by Philip Drinker,** a professor of engineering at the Harvard School of Public Health. His first test "patient" was a paralyzed cat in 1927; the first human used his lung in 1929.⁽⁷⁾

By 1936, there were 222 iron lungs throughout the world, including one at the Peiping Union Medical College. That lung saved and sustained the life of Frederick B. Sime, Jr., a very wealthy young man who was on a world cruise with his parents when polio struck him in Peiping. From then until his death 18 years later, the media reported every move of the "man in the iron lung" - his travels, hobbies, homes, marriage, and children.⁽⁷⁾

* In response to the devastating epidemics and deaths from bulbar polio, the prolonged management of respiratory failure by tracheostomy and long-term positive-pressure ventilation was perfected. The Engstrom ventilator - prototype of all positive-pressure ventilators used today - was designed in response to the polio crisis.⁽⁴⁾

** Another popular negative-pressure tank respirator was designed by Jack Emerson in 1931. According to Mr. Emerson, the first iron lung was built by Alfred F. Jones in 1864.⁽⁵⁾

Money and appropriate community-based supportive care were no problem for Snite, but they have been a major concern for ventilator-assisted individuals and their communities ever since. Economic considerations, not quality of life, have been the chief catalysts for action on their long-term care.

Saving money on the long-term care of polio patients scattered in hospitals around the country was the primary reason for developing regional respiratory polio centers during the epidemic years of the early 1950's.⁽⁹⁾ The centers, located in 16 teaching hospitals and medical schools around the country, met the needs of the increasing numbers of older and more severely paralyzed polio survivors. Contrary to the popular notion of polio as a child's disease, two-thirds of the patients with respiratory paralysis were young adults.⁽⁹⁾ Donations poured into the National Foundation for Infantile Paralysis which paid for everything at the centers: professional staff, inpatient and outpatient care, equipment and its maintenance, research, home care and modifications, and the salaries of attendants.

Again, saving money was the principal reason for developing a home care system for ventilator users in 1953. That first system was developed at Rancho Los Amigos, the Los Angeles County hospital, to save money on the care of 158 hospitalized ventilator-assisted patients.⁽¹³⁾ The savings were significant. The experiences should be studied carefully for they are equally applicable today. Community-based home care services cut the average hospital time from one year to seven months.⁽⁹⁾ Home care that included attendants, equipment maintenance, and other supportive services were one-tenth to one-fourth of hospital costs.^(9,11)

The regional centers engendered a very positive attitude and used a multidisciplinary team that included the staff, the patients, and their families.⁽³⁾ Before the patients went home, they were encouraged to make informed choices, to direct their own lives, to instruct others in the use of their ventilators, and to hire and train attendants. The centers functioned as an information resource for disabled individuals and their private physicians. It was estimated that, without the centers, 40 percent of those who went home would have had to remain institutionalized for the rest of their lives.⁽⁹⁾

Unfortunately, the centers were short-lived, because they were dependent upon financial support from a voluntary organization. The success of the polio vaccines curtailed donations to the National Foundation. By 1959, it had to close the centers and stop funding home care. However, Goldwater's Respiratory Rehabilitation Center (New York City) was able to survive because it was funded by the City of New York when the National Foundation withdrew its support. Rancho Los Amigos (Downey, CA) was able to continue to care for ventilator-assisted individuals because it was supported by the County of Los Angeles. The other National Foundation Respiratory Centers, which were in voluntary hospitals, were unable to continue because of the lack of funds to care for the long-term ventilator user.

The decade of the regional respiratory polio centers had a profound effect on the future development of critical care, pulmonary, and rehabilitation medicine.* Today these are the medical areas of expertise concerned about prolonged mechanical ventilation. With the closing of the regional centers, the medical leaders became the pioneers and teachers in new or evolving disciplines of physical medicine (physiatry), pulmonology, neonatology, anesthesia/intensive care (reanimation), and surgical specialties.⁽²⁾ Allied health professional team members, using their polio experiences and knowledge-base, enlarged their capacities to serve patients with other acute illness or chronic conditions that needed physical, occupational, and/or respiratory therapy. The pioneering advances in upper airway management and mechanical ventilation were the seeds for the growth of respiratory care techniques and technologies which stimulated and enabled modern advances in anesthesia, surgery, and prolonged life-support as we know it today. As a result, people with life-threatening, medical or surgical conditions who are primarily healthy - or even those with chronic underlying medical problems - can now benefit from applied technology in the acute care setting. Because of this, quality survival is now possible from illness that in previous

*Acknowledgement for the confirmation of this historical perspective and its significance is given to John E. Affeldt, M.D. Dr. Affeldt has had years of experience beginning with the era of paralytic polio to the application of respirators to patients with high spinal-cord injuries, obstructive lung disease, traumatic head injuries, and many other physiologic and pathologic causes of respiratory failure of a chronic nature. Dr. Affeldt was formerly Medical Director of Rancho Los Amigos, and the Department of Public Health (Los Angeles County). He is an innovator of the first polio respiratory center and an authority in public health. He is a recognized leader in the organizational and evaluation of health care delivery in the U.S.A. He currently serves as the President, and Joint Committee for Accreditation of Hospitals (JCAH).

generations was not the case. Even for those few survivors who are not cured, but remained technology-dependent, home support is possible today due to technology (curaiss, poncho, Tunicliffe jacket, positive pressure units, lightweight portable devices) suitable for home and travel use that was first developed for polio patients.

The organizational concepts that developed from the polio experience were as important as the technologic advances. Regional systems of health service delivery were created by those leaders of the polio era who could best understand their necessity. Examples include the regional intensive care unit, rehabilitation institute, spinal cord center, and trauma center. According to Affeldt, the successful elements of the polio centers of expertise (the interdisciplinary team approach, the concentration of resources, the multiple-purposes (clinical care, teaching, research)) served as models for evolving modern centers whose missions were devoted to complex, critical, acute or chronic illness.

Whatever happened to the polio patients? ⁽⁶⁾ The 1,756 respiratory polio survivors ⁽¹⁴⁾ could have been drains on society in the cocoon of institutional care, but for more than 30 years most of them have lived at home with non-professional attendants. They have lived full and useful lives as wage-earners, consumers, spouses, parents, and grandparents. ^(3,6,10,12) For 26 years, the Rehabilitation Gazette has documented their productive lives and contributions to their communities. Today, they are entering the ranks of the elderly and are facing new situations. ⁽⁸⁾

Experiences of these aging polio survivors are important to those who require ventilators because of other diseases and injuries. As examples, the experiences of two ventilator-dependent octogenarians, who began to use ventilators in their late seventies and who then progressed from intensive care to home and active community involvement, illustrate the influence of the polio experience, treatment, and technology:

Jacob Javits, former Republican senator from New York, has been on a ventilator since 1983 when he was 79, because of amyotrophic lateral sclerosis. An active board member of the ALS Foundation of New York City and a prolific speaker and writer, he says, "I have no feeling for a long life, but I have a great feeling about a useful life....I decided to work hard...and perhaps show other disabled people that there is life to be lived.... I still have my marbles. The great issues to which I devoted my life remain great issues. I have nothing better to do than to give my remaining strength to them."

Fay Daniels, who is now 81, was disabled by facio-scapulo-humeral dystrophy when she was a teenager, and she has been dependent upon a ventilator since 1971. Before that time, she had been an executive and a very active person. During the initial hospitalization she did not want to live, "In 1982 I decided to be myself again. I became active and I went home with attendant care.... Now, the only thing that is left of my body is my brain, but my I' continues."

Such life experiences prove that relatively simple devices are effective for long-term care, that it is unnecessary to move the hospital to the home, and that it is a mistake to try to withdraw persons from ventilator support who can continue to function in their daily lives only if they are not. Their lives demonstrate that with appropriate support services, training, and professional supervision, the family or non-professional attendants can manage the care of ventilator-assisted individuals in their own homes or alternative home-like settings without resorting to institutional solutions.

The productivity, creativity, and potential of polio survivors as healthy paralyzed people are proof of the human value as well as the economy of regional, community-based, individualized home care service systems for ventilator-assisted persons of all ages.

The history of prolonged mechanical ventilation - its origin with the polio patient - is one of how technology, which began for one purpose, can be used (or abused) for another: the critically- or terminally-ill elderly.

There have evolved only a few centers of expertise which can relate to the current practice. Dr. Barry Make directs one such unit which is unique because of experience with COPD. According to Make, it is precisely the polio and neurologically-impaired person that are today's major beneficiaries who require prolonged mechanical ventilation. Make, with other contributors to this OTA report, will help determine how prolonged mechanical ventilation is being applied today - with what success, difficulties, and cost. Nevertheless, this historical account, written by those responsible for making it happen, is how we have come to where we are today.

2) Definition of key concepts (Goldberg)

The functions of respiration are oxygenation (to deliver oxygen) and ventilation (to remove carbon dioxide). Respiratory failure is a life-threatening condition with a disorder in oxygenation and/or ventilation. It is determined by blood measurements of oxygen and carbon

dioxide, and it exists when these blood levels exceed expected normal ranges for age at given barometric pressure. It is arbitrary to choose the duration of time when an acute condition is considered long-term or chronic. Most physicians polled agreed that the time should be either 2 days, 2 weeks, 1 month, 6 weeks, or 3 months! The basis for their preference is the point in time when the condition has lasted long enough that it is anticipated it will last longer than anyone can reliably predict. This must be done on an individual case basis or by diagnostic category, taking multiple factors (including age) into consideration.

There have been other terms frequently used interchangeably with respiratory failure: pulmonary/ventilatory failure, pulmonary/respiratory insufficiency. As there is no accepted and preferable terminology, it is essential to define these terms each time they are used. In general, there is no difference among the terms ventilatory, respiratory, or pulmonary when used to describe breathing. However, some physicians consider chronic respiratory insufficiency as a distinct entity from chronic respiratory failure: the former is life-affecting rather than life-threatening. By this it is meant that a person will not die, but may not be able to live independently outside of an institution because of medical instability. If they do, they cannot function to their capacity because of inadequate oxygen delivery to vital organs and a build-up of carbon dioxide. This limits strength, vitality, and clearness of thought.

A ventilator is a mechanical aid for breathing: a device to augment or replace natural efforts of respiration. These devices were formerly called respirators, and in some institutions (e.g. Goldwater) and countries (e.g. England) they still are. As these devices evolved into more sophisticated life-support systems, and the need for better classification became evident, the term ventilator was introduced.^(15,16,17) Ventilators work either by (1) positive pressure applied to the natural airway (mouth positive pressure) or artificial airway (tracheostomy positive pressure) or by (2) negative pressure applied to the chest wall and/or abdomen (iron lung, curraiss, rocking bed).

The objective of mechanical ventilation is to reverse low oxygen (hypoxia) or high carbon dioxide (hypercarbia) due to inadequate spontaneous ventilation (hypoventilation). Normally, this correction is anticipated and accomplished over a few hours or days. If not, at some defined point (weeks), the need for a ventilator-assistance becomes "prolonged". As with the distinction of "chronic", "prolonged" refers an arbitrary duration of time. At this one can no longer reliably predict how long technology assistance will be used. The decision is made on an individual case basis and differs with each diagnostic category and clinical situation. In most cases, the situation initially requiring a ventilator was acute and prolonged use was not anticipated. In other cases (e.g. chronic illness), is anticipated and preferred to living without a ventilator. For this OTA Survey (Task #3), "prolonged" was arbitrarily chosen as two weeks. Although another duration of time could have been used, it was of interest to learn the outcome of patients who

require ventilator for this period of time. It was anticipated that this would be essentially the same group of patients that would also require ventilation at one month.

Once the requirement for mechanical ventilation is prolonged, and the condition becomes chronic, the ventilator-assisted person is considered to be ventilator-dependent. At this point, the condition may still be life-threatening (chronic respiratory failure). More often, the ventilator is used to achieve medical stability in order to reduce the number of major diagnostic decisions and/or therapeutic interventions required by the patient (chronic respiratory insufficiency). This permits for the patient more mental clarity, vigor, and ability to interact with the environment. In addition, it raises the option of an alternative to an expensive care unit.

3) Goals of ventilator care (Goldberg, Indihar)

The goals of ventilatory care are to:

1. Reverse hypoxia (low blood oxygen tension)
2. Reverse hypercarbia (high blood carbon dioxide tension)
3. Decrease the work of breathing
4. Prevent patient fatigue
5. Assist respiration in patients with decrease muscle strength (as in neurological disease)
6. Overcome small airway obstruction and/or low compliance (stiff lungs or chest wall)
7. Reverse atelectasis (small air sac collapse) unresponsive to conservative therapy

8.- Enhance physical and mental functional ability.

Mechanical ventilation may be applied to previously healthy elderly patients with acute respiratory failure due to pneumonia, atelectasis, severe bronchitis, heart attack with congestion or irregular rhythm, pulmonary edema, adult respiratory distress syndrome, usually with the anticipation of short-term use. Patients with underlying chronic disease of pulmonary, cardiovascular, neurological or other organ system (e.g. diabetes, hardening of the arteries, high blood pressure) may also require mechanical ventilation to reverse similar acute conditions. In an unexpected few, its application becomes unintentionally "prolonged". For example, the patient with COPD who develops acute respiratory failure as the result of a pneumonia may be placed on a ventilator contemplating its ultimate removal once the pneumonia resolves. However, such patients may not be weaned over a short period of time due to their underlying pulmonary or other disease process which mitigates against weaning (e.g. a primary neurologic disease (ALS) which results in progressive weakness). At the initial time of life-threatening acute respiratory failure, this was not anticipated. Prolonged use becomes the reality due to circumstances related to 1) the original cause (e.g. an especially virulent or antibiotic-resistant bacteria or virus; 2) the patient's response to therapy (e.g. an altered response due to impaired immunological ability or a less than desirable therapeutic response to drug management; or 3) the uniqueness of the situation (e.g. secondary complications resulting from unwanted or unexpected side-effects of the therapeutic regimen). In some instances, chronically-ill patients cannot be withdrawn from the mechanical device after the acute management due to progression of

their underlying disease process(es) or the extra effects the acute illness has had on the original condition (e.g. progressive neuromuscular weakness, progressive emphysema). Diagnoses in this category which specifically apply to the elderly population include amyotrophic lateral sclerosis, other degenerative neurologic disorders, cerebrovascular accidents, the aftermath of other organ system failure (renal, cardiac), plus a host of conditions in the cancer/lymphoma family.

The determination to initiate and continue to provide mechanical ventilation has, thus far, been an option open to the elderly patient. Indeed, it has been the goal of medical care to keep the ventilator-assisted individual sustained on these devices, presumably to enjoy life, grandchildren, family members, and to continue to be contributing members of society. This is particularly the case with the younger individual with great mental potential who may have been neurologically injured. It is also true of the elderly patient with a progressive chronic underlying condition who, with this support can continue to function in the community. For critically-ill elderly patients, the goal is to provide support during an anticipated finite period of organ system(s) failure. For terminally-ill elderly, the goal is to buy time for the patient and/or family who need it to prepare for the inevitable death. Thus far, the ethical application of humanitarian and medical principles has dictated that life-sustaining procedures, despite cost, are applied if the patient and his family determines that, indeed, this is their desire.

Unfortunately, the application of life-saving technologies to the critically- and terminally-ill patient has been seen with some degree of frequency in the past. In many instances, the goals of this treatment were not readily apparent. The future education of medical and social service personnel should encourage that life-saving technology always be applied to a critically-ill patient by definition. The major ethical dilemma occurs in the patient with an incurable disease process who, for one reason or another, opts to having the life-saving technology applied to them.

4) Range of patients-adult experience (Alba, Indihar)

In the late 70's, the Bethesda Lutheran Medical Center, St. Paul, did a complete analysis of Minnesota and bordering states of the Upper Midwest region.^(18,19) Indihar's studies found that many patients who required prolonged mechanical ventilation could not receive adequate care in loving, safe, and home-like environments; their sole alternative was "living" in an intensive care unit. The Foundation for Health Care Evaluation, the Minneapolis-St. Paul Regional Professional Standards Review Organization (PSRO), Medicare, and Medicaid (Minnesota Welfare) supported the Prolonged Respiratory Care Unit (PRCU), which permitted prospective reimbursement based on defined categories of care which were more favorable than regular hospital intensive care unit (ICU) rates. The following updated statistics from the PRCU reflect admissions since the origin of the PRCU in 1979, the majority of which came from regional state-wide medical centers other than Bethesda Lutheran Medical Center and from neighboring states of North and South Dakota, Iowa, Wisconsin, Illinois, and Michigan, the referral area of the Upper Midwest (See Tables).

PROLONGED RESPIRATORY CARE UNITAVERAGE DAILY CENSUS

1980 (Jan-Dec)	16.7
1981 "	23.8
1982 "	27.0
1983 "	27.0
1984 "	21.0
1985 (Jan-May)	23.0

AGE RANGE

15-20	5	
21-30	18	
31-40	12	
41-50	21	
51-60	48	
61-70	130	
71-80	97	
81-90	24	
TOTAL	355	
FEMALE	187	52.6%
MALE	168	47.3%

DISCHARGE ACTIVITY

August, 1979 - May, 1985

Death	35.5%
Home	29.0%
Nursing Home	7.0%
Intensive Care	19.3%
Other In-Pt. Units	3.8%
Other Hospitals	3.5%
Rehabilitation Units	1.2%

LENGTH OF STAY

Range: 2 to 2,054 days

OTA Task 2

Contract 533-4935.0

10/15/85

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ADMISSION ACTIVITY

Number	355
Specialist Type:	
Internal Medicine	259
Family Practice	57
Pulmonary Specialist	37
Other	2
TOTAL	355

DIAGNOSTIC DATA

COPD	271
Muscular Dystrophy	6
Closed Head Trauma	6
Quadraplegia Trauma	22
Quadraplegia, Polio	7
Charcot Marie Tooth Synd.	3
Multiple Sclerosis	1
Amytrophic Lateral Sclerosis	7
Guillian Barre	3
Restrictive Lung Disease	8
Central Hypoventilation	1
Neurological, Other	3
TOTAL	355

These data, which depict a cross-section of patient ages and diseases, indicate the wide variety of patients who require prolonged mechanical ventilation. A number of these patients are absolutely unweanable; however, they have accommodated to their disease process. Of particular interest are the 29% of patients who were discharged home. These individuals enjoy the comforts of family life, despite the hindrances of mechanical ventilation. Of course, a qualified primary caregiver must be supplied to these individuals; often this is a dedicated and interested family member. However, support from many home care agencies is available to give the primary caregiver relief, additional aid, nursing help, etc.

A number of Indihar's patients were totally weaned from ventilator support during their stay on the prolonged unit. Weaning, the process of gradual and purposeful withdrawal from a mechanical ventilator, requires patient, dedicated and skillful care. If weaning is a realistic goal, it must be accomplished in the hospital setting, where the patient feels secure. Weaning has never, in Indihar's experience, been accomplished in the home setting, due to the insecurity the patient experiences without the surrounding safety of the hospital/PRCU staff and emergency care available.*

*My recent experience has demonstrated that with appropriate planning, available personnel, and suitable technologies, major medical adjustments and prescriptions can be accomplished in the home setting which is far more natural and appropriate to the level of activity of the patient. It also saves money. (Goldberg)

Some unweanable patients must reside at the PRCU due to the difficulty experienced in obtaining adequate, safe placement in a nursing facility or the lack of a willing primary caregiver to provide care in the patient's home setting. It is interesting to note how many of these patients, when presented in an honest manner with the options, decide to be resuscitated despite their dependence on mechanical ventilation!

As reflected in later data (See PRCU Rehabilitation Data - Appendix), the vast majority of the patients (greater than 80%) were alert and mentally competent. The level of functioning, of course, varied with the diagnosis. For instance, a quadriplegic patient required ALL activities of daily living to be provided by nursing/physical therapy/respiratory therapy personnel. The patients with multiple sclerosis, with adaptive wheelchairs and other devices to control their environment, could get about the unit and control lights, TV, radio, and call systems from their beds; self care, feeding, etc., required assistance. Those patients with closed head trauma were totally dependent on ancillary personnel for all care. However, the greatest number of patients, those with the diagnoses of chronic obstructive or restrictive lung disease, were dependent on ancillary health personnel to varying degrees. Virtually 100% of these individuals required a ventilator: 80% for 24 hours/day, and 20% for 8-12 hours per day (this latter statistic is skewed by our weaning attempts). The prognosis, too, is quite variable. These statistics are revealed in the PRCU Rehabilitation Statistics. (Appendix).

Is the Bethesda experience typical or unusual? The PRCU is a unique unit because it was specially designated for a target population which required long-term respiratory care and could not go home or to other institutional settings because of special needs. In that regard, the PRCU made available a new option when only less satisfactory ones before existed. However, the Bethesda experience demonstrates what a regional referral center can accomplish in cost-savings and other benefits to a target population which already exists. Their experience can provide a better understanding of the population-at-large of ventilator-assisted persons.

Can the Bethesda experience be extrapolated to the national level? The Upper Midwest does not have a statistical preponderance of any particular disease entity. Specially-designated programs do exist elsewhere and their experience can put those of the PRCU into perspective. At Boston University, Make et al have reported on their concept and initial experience in the rehabilitation of ventilator-dependent patients.⁽²⁰⁾ The Respiratory Care Center (RCC) opened in 1981; it featured the multidisciplinary approach to evaluation, management, and discharge planning. The rehabilitation focus of the RCC resulted in the self-sufficiency of the patients at home. Of interest, the initial report of 16 patients (10 COPD, 6 restrictive disorders) included only two over the age of 65. At the Institute of Research and Rehabilitation, Houston, TX, Splaingard et al have reported over twenty years of experience with home positive pressure ventilation (1962-1983).⁽²¹⁾ Their experience with prolonged mechanical ventilation began during the polio era and expanded for a variety of other conditions: 26 patients had spinal cord injury and the remaining 21 had a variety of

cardiac, neuromuscular, central nervous system control of breathing and miscellaneous disorders. Again, the reality of this often quoted experience is one of a limited number of elderly: 1/47 patients.

The Goldwater experience⁽²²⁾ with elderly patients who require prolonged mechanical ventilation does incorporate the consideration of physical and mental functioning at the time treatment is considered. All patients must have some ability to communicate either verbally, with gestures, or with augmentative communication devices. Among the neurologic cases, some are quadriplegic; some have use of the upper extremities. Within a matter of weeks, months, or years, the patient's cerebral status may worsen either from intrinsic disease which required the ventilator in the first place or from episodes of cerebral hypoxia (from intermittent respiratory infection, cardiopulmonary arrest) or cerebral atherosclerosis. The prognosis in all cases without the ventilator is death. However, cases such as spinal cord injury and Guillain Barre do in many instances show improvement to the point that they are either weaned off the respirator or partially-weaned (less than 24 hrs/day).

Alba reports that her pulmonologist colleague (Lilia Gay, M.D.) has 9 elderly COPD patients who require prolonged mechanical ventilation: 8 for 24 hrs/day, 1 for 12 hrs/day. These 9 patients are alert, bright, and many of them were in the past professional people. They either have no family or their families fear taking them home and caring for them. There are no health related facilities or nursing homes which are equipped or staffed to care for patients on respirators. With rare exceptions, the facility in

Because of the sparcity of reported cases, one must reconsider if, in fact, there is a large number of elderly persons requiring prolonged mechanical ventilation. OTA Task #3 (Data on Utilization and Cost) was undertaken to get some better idea of the incidence of prolonged mechanical ventilation of the elderly and if possible, of the quality of functioning, mental status, prognosis, and degree of technology-dependency of this population. To the knowledge of the contributors of this project, this will have been the first concerted effort of its kind in the U.S.A. directed to any age group who are dependent upon mechanical ventilation.

B. MODERN EQUIPMENT AND SETTINGS IN WHICH THEY ARE USED

1) How ventilators work (Goldberg/Indihar)

Ventilators have 5 major components:

- 1) Power source: Source of energy to run the machine (electric motor, high-pressure gas);
- 2) Force generator: Mechanism that moves the gas (piston/cylinder, turbine-compressor, high pressure gas);
- 3) Control system: Adjustable variables that determine the characteristic of the breath delivered (volume, rate, flow, etc.);
- 4) Delivery system: Tubing, valves, and connections that link the machine and patient (includes humidification); and
- 5) Alarm system: Devices that warn patient or caregiver of machine/patient malfunction.

Ventilators are classified by the primary variable that is pre-determined. This function (volume, pressure, time) is "pre-set", and it determines the delivered breath (tidal volume). For example, with a volume pre-set ventilator*, the inspire tidal volume delivered to the patient is determined by dialing a volume. A pressure pre-set ventilator determines delivered tidal volume by dialing a pressure.

Ventilator modes determine the degree of control the machine will have in the breathing cycle. Control Ventilation provides total respiratory support; the ventilator cycling is independent of the patient's desire and

*Prior to standard terminology,⁽¹⁶⁾ such ventilators were classified as volume-cycled, volume-regulated, and volume-limited ventilators. Similarly, pressure ventilators, pressure-cycled, pressure-regulated, etc. Terminology is still interchangeable.⁽²³⁾

is based on the clinician's assessment of patient need. This mode is used for the unconscious patient or when spontaneous ventilation is significantly depressed. Assisted Ventilation is used when the patient's efforts are sufficient to initiate a breath; this is sensed by the machine, which "assists" the patient by providing airflow as determined by the the pre-set variable (e.g. volume, pressure, time). Assist-Control senses if a patient has not taken a breath for a certain period of time, and then one is provided. However, if the patient does make the effort, the machine will sense and "assist" it. Intermittent Mandatory Ventilation (IMV) allows the patient to spontaneously breathe while connected to the ventilatory circuit; at some pre-determined time, the machine will intermittently deliver a breathe. IMV cycles are independent of the patient's own breathing effort; at times, this may be counter to the patient's needs and efforts. Synchronized Intermittent Mandatory Ventilation (SIMV) permits the patient to breathe at his own rate, but the intermittent mandatory breaths are synchronized to occur with the patient's own efforts. This is considered by some to be the most natural way to maintain patient's independence, adequacy of ventilation, and maintenance of respiratory muscle strength. Others have observed that the prolonged use of this mode on modern sophisticated ventilators impedes the "weaning" process.

Once the type of ventilator and ventilator mode has been selected, the volume of the breath (or the pressure to generate the breath) and rate of breathing (breaths per minute) are chosen in order to provide for the patient's metabolic and oxygen needs. Also, the ratio of inspiratory to expiratory time may be determined (I:E Ratio). Humidification must be

supplemented to high flow air/oxygen mixtures to prevent drying of the tracheal mucous membranes. Positive End-Expiratory Pressure (PEEP) can also be added to provide the patient with a small amount of pressure at the end of expiration to prevent the inevitable collapse of small airways and air sacs (atelectasis) that tends to occur in the bed-ridden and immobile patient. PEEP is used more in the acute situation prior to achieving medical stability. For prolonged mechanical ventilation, a program of chest physical therapy is more effective in accomplishing this goal.^(24,25) Thus, simpler devices (without PEEP) may be used, and the patient (young and old alike) can take a more active part in self-care.

2) Alternative methods; comparison of available mechanical devices;
Indications and contraindications (Alba)⁽²⁶⁾

Mechanical aids for breathing may also be described according to whether the apparatus 1) operates by positive or negative pressure; 2) produces an active inspiration and/or active expiration; 3) is applied to the natural airway, artificial airway, or body (chest/abdomen); and 4) is cyclical or non-cycling.

If the patient requires a permanent artificial airway (tracheostomy) and the tracheostomy opening is not too small (i.e. only needed to clear mucous), the patient can choose to use tracheal intermittent positive

pressure ventilation (TIPPV*) for sleep, and mouth intermittent positive pressure (MIPPV**) or a pneumobelt*** during waking hours. A patient might elect to use MIPPV during the day, because it provides the opportunity to plug the tracheostomy tube, thereby producing less drying and irritation to tracheal mucous membranes, and allowing glossopharyngeal breathing**** if capable. The use of the pneumobelt during the day would be reserved for the patient who can tolerate a plugged tracheostomy tube, and for whom the relatively small breath provided by the pneumobelt in the semi-sitting

*TIPPV is positive pressure breathing which results from connecting a cycling mechanical aid for breathing to the patient by a tracheostomy. The ventilator is a simple volume pre-set one with only control of volume and rate. (e.g. Thompson Bantam)

**MIPPV is positive pressure breathing which results from connecting a cycling or non-cycling device to the patient by a mouthpiece (straw) or face mask (during sleep). The patient can maintain the natural airway and takes a more active part in their own breathing. As with TIPPV, the devices are simple, delivering either a cycled breath (Thompson Bantam) or continuous flow (Thompson Zephyr).

***A pneumbelt is an inflatable bladder worn around the abdomen. It is a positive-pressure device which augments exhalation for the patient in the sitting position. It is used with a cycling portable ventilator (Thompson Bantam).

****Glossopharyngeal (frog) breathing is a technique discovered by polio patients who use their mouth and throat to gulp small quantities of air at a rapid rate. This allows them periods of spontaneous ventilation and the safety factor of "free-time" off mechanical ventilation.

position is adequate. At the present time, a body respirator* (tank, iron lung) is not used by the patient with a tracheostomy tube, because it is easier to attach a mechanical ventilator to the tracheostomy tube, and the patient can be more comfortable in bed and while mobile (walking, electric wheelchair). Alternatively, the patient may elect to use TIPPV around the clock. If the patient has weak mouth/throat (oropharyngeal) muscles, a central control of breathing disorder, upper airway obstruction, any disturbances of consciousness (due to critical illness or acute anxiety), and/or is unable to cooperate with MIPPV, the decision will be made to have the patient use TIPPV even during waking hours.

If the patient does not have a tracheostomy, then either MIPPV or body ventilators may be used alone or in combination, depending on whether the patient requires a breath (tidal volume) greater than average (because of intrinsic lung disease and/or increased metabolic energy needs). If a larger tidal volume is needed, then this can be provided by intermittent positive pressure ventilation or body respirators (iron lung or poncho). The iron lung is bulky, and the patient is relatively inaccessible for intensive nursing care and monitoring. The poncho allows the patient to remain on a regular hospital bed, but it gives somewhat less of a breath, because of the sucking in of the wrap under the grid over the upper anterior

*A body respirator is a device that intermittently cycles negative pressure around the thorax and abdomen, this results in a breath taken through the natural airway.

**The poncho (body jacket, envelope) is a cloth or plastic wrap which is placed around the body permitting a space in which is intermittently-cycled negative pressure.

chest wall, which prevents the upper lobes of the lungs from being fully inflated. If the patient using any of these body respirators has only a short period of time to spontaneously breathe, and the device must be shut off for a variety of reasons, the patient should be able to use MIPPV during that interval from any available cycling positive pressure ventilator.

If the patient requires an average tidal volume, this can be provided by a rocking bed,* cuirass,** or pneumobelt. The rocking bed provides a feeling of freedom and movement. Persons who have the ability to transfer themselves independently from a regular hospital bed to a wheelchair may not be able to do this from the rocking bed. The rocking bed ventilates mainly the lower lung lobes with passive excursion of the diaphragm. The cuirass similarly causes passive excursion of the diaphragm and some passive expansion of the lower rib cage. If the patient is in a semi-sitting or sitting position, the pneumobelt ventilates mainly the lower lobes, and provides no more tidal volume than functioning abdominal muscles.

* The rocking bed is a hospital-size bed which alternates its position up and down. The degree (angle) of the position determines the size of the breath, which is created by the effects of gravity on the bowels and diaphragm. The breathing rate is determined by the number of alterations per minute.

** The cuirass (turtle shell) is a plastic cover over the chest and/or abdomen that provides a space in which is intermittently cycled negative pressure.

Most patients with neuromuscular disease today prefer the use of MIPPV, both during sleep and waking hours. Many ingenious ways of attaching the breathing tubing to the mouth, nose, or both are being developed by these patients themselves. These are usually designed by patients working with friends who are engineers, dentists, etc. and made with simple materials (e.g. plastic) which meet the physical and functional needs of the patient.

Patients who use mouth or nose IPPV during sleep, or those who sleep with TIPPV with a deflated cuff* on their tracheostomy, must be watched carefully for upper airway leak. The ventilator is usually set at a higher pressure or tidal volume to compensate for the leak. The patient can usually control the degree of leak quite well in sleep, but this is a conditioned reflex, and close monitoring is needed during the training period. In some patients, the variable upper airway leak (position, awake/asleep) becomes the major management challenge.

There has been a proliferation of compact, lightweight, volume-pressure ventilators since 1978. This is a major advance from the original high-energy requiring portable ventilator and the bulky more sophisticated

* Tracheostomies often have cuffs (small balloons) at the lower end to make a tight seal with the tracheal wall. For patients who can cough, it is safer to leave these cuffs deflated (or not use them). This reduces injury to tracheal mucous membrane and permits the patient to speak. Some patients do need them for adequate ventilation or to protect the lung from soiling from gastrointestinal contents which leave the stomach, rise up the esophagus, enter the trachea, and descend into the lungs.

stationary (console) ventilator. The portable device has an internal battery which allows it to operate for at least an hour, if the external battery is no longer functioning or has not been attached. The ventilator can also run for 24 hours on an external battery. With this this type of portable ventilator, the elderly patient can move about on a wheel chair or by walking and carrying the ventilator on a small wagon. These portable devices have made it far easier to permit mobility and can be used in a non-hospital setting. Up to now, they have been designed to be so simple that non-professionals can use them under the direction of a physician, nurse or respiratory therapist. A more detailed analysis of the characteristics of each type of portable IPPV respirators on the market today is attached (Appendix).

3) Patient-Machine Interface (Goldberg, Indihar)

As the above discussion describes, patients can be ventilated by positive pressure applied to the natural airway (mouth, nose) or artificial airway (tracheostomy). The patient can also be ventilated by negative pressure applied to the thorax and/or abdomen; under such a situation, the natural air-way is intact and serves only as the port of entry and exit of gas, not the connection to the device.

There are important reasons why it is best to maintain the natural airway if at all possible. Serious complications of artificial airways can be avoided (e.g. tracheal stenosis, erosion) but, even more importantly, normal function can be maintained. The natural airway provides pro-

tection against infection, essential humidification and heating of inspired gas, a "physiologic" positive end-expiratory pressure, and the means of spontaneous cough and clearing of secretions as well as normal speech. If the patient is able to breath via the natural airway, he/she can play a more active role in their self-care as well as in their assisted breathing. It has been shown for years that prolonged mechanical ventilation can be accomplished - day or night - using the natural airway. This requires awareness, desire, and motivation; instruction on how to do it; and some innovative (but simple) technology to accomplish it. This kind of breathing (connecting a ventilator to the mouth or nose) also requires a conscious patient whose breathing requirements (volume/pressure) are not excessive, who can handle their own secretions (which are less without an irritating artificial airway in place), and who has a normal control of breathing regulation.

Some patients may not be suitable for ventilation via the mouth or nose, and they will need a long-term artificial airway which will bypass the natural airway. In the acute situation, this can be accomplished for hours or a few days by endotracheal intubation. The risk of short-term intubation are less than with tracheostomy⁽¹⁵⁾. However, with time, the rate of complications becomes excessive, and, because of the difficulties involved with endotracheal tube stabilization, the risk can become life-threatening. Thus, the tracheostomy is the only long-term artificial airway indicated. It should be used in the patient with inadequate level of consciousness and/or control of breathing, poor control of mouth and pharyngeal muscles, inability

to handle secretions, and or high ventilation requirements (pressure/volume) that cannot be delivered via the natural airway.

4) Monitoring technology (Goldberg, Indihar)

All patients who require prolonged mechanical ventilation must have surveillance to be certain that their physiologic requirements for breathing are met. This can be done by observation of caregivers and by technology.

Physiologic monitors determine whether or not a given body function is appropriate (e.g. heart rate, breathing rate); if pre-set limits are exceeded (high and/or low), characteristic alarms (light, sound) will alert another person that there is a dangerous and perhaps life-threatening situation. Non-physiologic monitors determine whether or not a given mechanical function or physical variable is appropriate (e.g. pressure, volume temperature, exhaled gas composition); if pre-set limits are exceeded (high and/or low), other characteristic alarms will bring immediate attention to determine the reason why (is it the patient or the machine?).

Young and elderly patients alike require such surveillance. The degree of surveillance does not depend upon age, but the medical condition. If a patient has limited "free-time" (time when spontaneous natural efforts to breathe can sustain life), the surveillance must be greater both by human observation and technology. Under such circumstances, it is advisable to have more than one means of surveillance based on more than one parameter. This is far more important than the degree of sophistication of the monitor. Usually ventilators have built in some monitoring capacity; to prevent

life-threatening situations, and reduce the chance of complications of prolonged mechanical ventilation, these monitors can be supplemented by others commercially available. However, often simple devices can be adapted for this purpose. Adaptations must be made by a knowledgeable biomedical engineer or respiratory technician. For instance, the low pressure, high pressure, and disconnect alarms built into all machines can be amplified and hooked into a light system over the door or central desk. Also, audible alarms can be amplified so that they can be heard some distance from the machine itself. A patient-driven switch/buzz communication system or commercially-available intercom system are two other examples.

A very special alarm system has been installed at the Prolonged Respiratory Care Unit at Bethesda Lutheran Hospital, St. Paul, Minnesota: the Respiratory Intensive Care System (RICS). This system, through a tube attached to the patient's tracheostomy, samples gas exhaled at various intervals of time. The sample is analyzed automatically for the exhaled carbon dioxide; the results are stored in a computer, which has a range for each patient. The alarm sounds if the patient's limits are exceeded. This device is not practical except for the largest institutional setting, due to the complexity and expense of the equipment.*

*Another alarm system, designed by Rattenborg, uses modem and telephone line. This permits the monitoring of ventilator function and its transmission to a central area. (27)

Monitoring devices are not effective unless people are prepared to interpret the alarms and correct the condition. In some instances, the patient's problems require a great deal of searching and elimination to determine the cause of the alarm. Primary caregivers in the home or alternative community setting must be trained to provide this type of expert care, and immediate emergency backup is required.

Alarm and monitoring devices have a special application to the elderly patient who is often debilitated and unable to operate conventional alarm buttons. Also, regardless of age, high pressure and low pressure measurements are not measurable by the patients themselves; rather, built-in ventilator monitoring systems are necessary to alert the health care practitioner to potential or real problems (i.e. disconnect of the tubing from the patient, build up of secretions in the bronchial tubes requiring suctioning, etc.).

5) Preferred technology for elderly (Alba, Goldberg, Indihar)

The technology preferred for the elderly depends not on age but on the etiology and severity of the patient's disease process(es) and the current medical condition. If an elderly patient requires mechanical ventilation, a device with adequate alarm capability is essential. This would reduce the likelihood of complications due to technical failure of the machine and would alert the caregivers of change in the general condition of the patient. According to Indihar, if a patient is at all self-sufficient, a portable ventilator is quite satisfactory, and would permit the

elderly person a more active life. However, if the elderly patient is infirm, not self-sufficient, and not medically knowledgeable, a non-portable (console) ventilator with multiple alarms must be utilized (low pressure, low volume, high pressure, apnea). The elderly will also need devices to provide humidity, oxygen and medical air, as well as supplies for appropriate artificial airway management.

The experience at Goldwater with patients over 65 years of age who require continuous mechanical ventilation demonstrates that the elderly usually require a tracheostomy (TIPPV). This is true both for the elderly patient with intrinsic lung disease (COPD) and neuromuscular disorders. There are a few exceptions when elderly patients with progressive respiratory insufficiency can begin for 1-3 years with MIPPV. According to Dr. Alba, this is attributable to the physiology of aging (poorer diffusion, decreased functional reserve), reduced strength and ability to cough, diminished tolerance to infection, and the presence of other organ system disorders.

It must be recognized that at 70 years of age, the normal individual has approximately 50% of the vital capacity* and 40% of the maximal voluntary ventilation** of youth.⁽²⁸⁾ Diffusion capacity*** also decreases with every decade of life.⁽²⁹⁾ Under quiet conditions, with youthful lungs, only 15% of

* The vital capacity is the largest possible breath one can take.

** The maximum voluntary ventilation is the largest amount of gas that can be breathed in and out within one minute.

*** Diffusion capacity is the function of exchanging oxygen and carbon dioxide between air sacs and small blood vessels in the lung.

the vital capacity is needed for ventilation.⁽³⁰⁾ Given the aging pulmonary system and superimposed illness, it is understandable why the elderly patient may usually require a larger than average tidal volume. The currently available portable volume ventilators can meet these requirements with supplementary monitoring devices. For safety, the equipment and its use must be fully explained to the patient, family members, and caregivers, and their classroom education and bedside experience well-evaluated and documented.

Goldberg has found that the currently available state-of-the-art portable ventilator is not adequate to meet safety requirements for home care for children who depend upon prolonged mechanical ventilation. Portable ventilators have suddenly failed completely without warning, deviated from the desired written respiratory prescription, and have met not all the functional needs of the children at home. In order to protect these children from unnecessary risk, home care programs require more than one device in the home, the second device preferably being a console ventilator. There is a very great need to evaluate available portable technology and to review the experience of others with its use before its application becomes more widespread.* There is also great need for guidelines for ventilator care in the home and at alternative community sites.**

*This is currently under consideration by the American Society of Testing and Materials, F29.03.09

**This is currently underway by an ad hoc committee of the Respiratory Care Section of the American College of Chest Physicians.

6) Complexity of equipment; feasibility of self-care, care by non-professionals
(Alba, Goldberg, Indihar)

Respiratory equipment requires that a caregiver must clean and examine it daily, tubing must be emptied of water frequently, and humidifiers changed on schedule. On occasion, mechanical problems need to be tended to immediately. For patient safety, and to reduce the number of malfunctions, regular equipment maintenance must be provided and backup emergency service assured by a home maintenance contract.

Much can be accomplished by a properly trained family member, but the time required in constant attendance to an elderly patient by a family member (spouse, son, daughter) is impossible. To provide under such circumstances, other supplementary caregivers are essential, and respite care alternatives should be made available. Self care, of course, can be one answer. However, this is only true if the elderly patient is partially ventilator-dependent: i.e. on the ventilator only at night and able to be off the ventilator for short periods during the day. Generally, for the patient who requires 24-hour mechanical ventilation, self-care is impossible and not a goal of treatment (Indihar). This opinion is in contrast to international experience which demonstrated that self-care up to the physical capacity of the patient is an essential success factor in home care and is possibly even for patients who must be ventilated day and night.⁽³¹⁾

In Indihar's experience, only the most sophisticated non-medical personnel have been able to handle complex medical problems with complex machinery. In many instances, even professionals have difficulty under such situations and

rehospitalization has been necessary. Those best elderly candidates for home care by non-medical personnel have a combination of a disease (stable) and personality (intelligent, self-sufficient) that enables them to cope with crisis.

Non-professionals can provide care in the home. However, an adequate care program must be established with professionals. Many home health-care agencies are available who can provide respiratory therapists, nurses, aides, and home-health care attendants to assist the primary caregiver in the home. However, up to now, such alternative caregivers have not been eligible for reimbursement by public or private funding policies. In order to assure the cost-saving and appropriate utilization of such alternative caregivers, a care monitoring system must be established to monitor the situation at home (quality-assurance).⁽³¹⁾

For more than five years in New York City, Concepts of Independence, Inc.* has managed the financial arrangements for severely-disabled, self-directing persons in the community who locate, hire, and train their own personal care attendants (Appendix). The Board of Directors are over 90% quadriplegic and ventilator-users, the president and vice-president included. At present, Concepts has over 210 clients and an annual budget of \$5 million. They service 37 ventilator-users, including six with tracheostomies. Initially,

* Concepts of Independence, Inc. 853 Broadway, Suite 1920, New York, NY 10003
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patients have the training for their future attendants done by the hospital which discharges them; after that, the patients are expected to provide ongoing training for any new attendants they hire. Home care providers (Visiting Nurse Association/Public Health Nurse) visit the home once every six months. The durable medical equipment (DME) vendor, who has rented the ventilator and its accessories, visits the home once every six months or as needed for equipment replacement and repair. The ventilator user is expected to teach the attendant to maintain the equipment in good condition. Concepts has demonstrated that for the medically-stable adult ventilator users a personal care attendant can be a very satisfactory caregiver*. Their clients at home are very proud of their autonomy.

*In April, 1985 the New York State Department of Social Services enacted new regulations to govern the provision of personal care services to the disabled in the home. According to these regulations the provision of care to a ventilator-user and to a tracheostomized client would be given by a Level III home health aide with frequent visits to the home by a supervisory registered nurse. Enclosed is a copy of these regulations (Appendix). Concepts of Independence, Inc., has obtained a waiver from these regulations. The self-directing client may continue in New York State to hire at the level of an attendant if he so desires. It is Alba's contention that if family members or the client (who are non-professional) can be taught to operate even complex ventilator equipment used in the home, and they can be given complete charge, a client can be left alone with other non-professionals who have shown the motivation to learn and to care.

Can non-professionals provide care in community-based alternatives to the home? The answer is, yes. In France, a specially-designated category of caregiver with a government-authorized salary (\$4.40/hr. in 1985) has become available for care under supervision for ventilator-dependent adults in group living arrangements. Such caregivers have been trained extensively by regional associations and are under the direction of professionals. This has remarkably opened the option for community health care for such technology-dependent persons. (31)

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 3. DATA ON UTILIZATION AND COST

October 15, 1985

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 3. DATA ON UTILIZATION AND COST

The questions raised by OTA concerning the data on utilization and cost were answered by a group initiative coordinated by The Center for Health Administration Studies, Graduate School of Business, University of Chicago. The major contributors to the enclosed document are:

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Contract 533-4935.0

041537

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Acknowledgements

Special recognition is given to the Chicago Lung Association and to the following officers who have made a personal commitment to the OTA Study and authorized the consultation of Ann Koterla. This made possible her participation as a major contribution by the Chicago Lung Association:

John L. Kirkwood, Executive Director
Richard L. Hughes, MD, Past-President
Karl F. Nygren, President

Special recognition is also given to the American Association for Respiratory Therapy and Sam Giordano, Executive Director, who conducted a national survey of the membership for the purpose of this OTA Study.

Appreciation is also noted for the assistance of Dr. Joseph M. Kaufert, PhD, Department of Social and Preventative Medicine, University of Manitoba, Winnipeg. Dr. Kaufert provided models which helped in the initial phase of design of this survey.

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OFFICE OF TECHNOLOGY ASSESSMENT

Life Sustaining Technologies and the Elderly

Prolonged Mechanical Ventilation

Task 3. Data on Utilization and Cost

FINAL REPORT

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*This document supercedes the September 1985 preliminary report.

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INTRODUCTION*

In the spring of 1985 the Office of Technology Assessment (OTA) issued a call for information on life-sustaining technologies and the elderly, with particular emphasis on the use of mechanical ventilation for chronically ill elderly patients and for those acutely ill elderly whose dependence on ventilatory support was prolonged (See OTA, "Life-Sustaining Technologies and the Elderly: Prolonged Mechanical Ventilation--Statement of Work."). Dr. Allen I. Goldberg, Medical Director, Division of Respiratory Care, The Children's Memorial Hospital, Chicago, responded to this call for information and asked the Center for Health Administration Studies (CHAS), The University of Chicago, to participate in Task 3, specified in the OTA Statement of Work for this project. Task 3 involved a review and interpretation of available data on the utilization and cost of services for elderly individuals on prolonged ventilator support and within limited time and funds constraints, the collection and analysis of other relevant data on the prevalence of elderly ventilator assisted individuals (VAIs) and their utilization and cost experience.

This report summarizes the results of the work on Task 3 by the Center staff and their colleagues during the months of July and August, 1985.

* This section was principally prepared by Lu Ann Aday, Ph.D., Research Associate (Associate Professor), Associate Director for Research.

Three tiers of data collection--at a national, regional and community level--were carried out in connection with Task 3. Two data gathering efforts at the national level are reported in Part I of this report: (1) the comparison of results from a 1983 national survey conducted by the American Association of Respiratory Therapists (AART) of the numbers of ventilator assisted individuals identified by state AART representatives with a comparable study conducted in July 1985 and (2) a national data inventory of over fifty organizations that deal directly or indirectly with the health care of the elderly to determine the availability of extant national data bases on this population.

At the regional level eleven institutions representative of seven regions of the country and Canada were identified by OTA and Dr. Goldberg as major providers of care for ventilator assisted individuals in their respective areas. These institutions were contacted and detailed data on the age, diagnosis, length of stay, degree of ventilator dependency, and source of payment of elderly VAIs served by ten of these institutions in a randomly selected week during the study period were collected. These data from the regional institutions case studies are summarized in Part II of the report, as is an overview of other relevant issues in caring for this population identified by the regional case study site representatives.

Part III of the report summarizes the results of case studies conducted in two major metropolitan areas--Chicago and New York--with particular emphasis on the network of institutions that serve elderly VAIs in these cities.

The analyses summarized here provide a variety of perspectives--at a national, regional and community level--of what is known about this population: how many there are, their age distributions, medical problems, how they pay for their care, and the issues that the patients themselves, their families, and the institutions and professionals caring for them confront. It represents a modest start, with limited time and resources, in providing systematic data on the elderly sustained on prolonged mechanical ventilation, where little or no information existed before.

PART I
NATIONAL DATA INVENTORY

AMERICAN ASSOCIATION OF RESPIRATORY THERAPISTS (AART)
SURVEY OF VENTILATOR ASSISTED INDIVIDUALS:
COMPARISON OF 1983 AND 1985 SURVEYS*

Introduction

As part of the Office of Technology Assessment's study of prolonged mechanical ventilation in the elderly, the American Association of Respiratory Therapists (AART) and its Executive Director, Sam Giordano, repeated its 1983 survey of ventilator dependent (or assisted)** individuals in the United States. Each of the AART state representatives were asked to complete a questionnaire comparable to that used in the 1983 survey (Appendix A-AART Questionnaire). In Table 1 these data are summarized. Table 2 displays the 1985 data by census region and the rates per 100,000 elderly for VAIs in those regions. The discussion that follows summarizes these data from the two surveys.

* This section was principally prepared by Marlene J. Aitken, M.A.M.S., OTR/L. The author gratefully acknowledges the data provided by Sam Giordano, Executive Director of the American Association of Respiratory Therapists, used in the analyses reported here.

** For the purposes of this report, the term ventilator assisted individuals (VAIs) will be used.

TABLE 1.

NATIONAL DATA INVENTORY
AART SURVEY OF VENTILATOR ASSISTED INDIVIDUALS
Comparison of 1983 and 1985 Data

<u>VARIABLE</u>	<u>1983</u>	<u>1985</u>
STATES REPORTING	21 (42%)	37 (74%)
TOTAL VAIs REPORTED	2272 (HOSPITAL ONLY)	3771 (HOME & HOSPITAL & OTHER)
TOTAL IN HOSPITAL	2272	2379
	% (N=)	% (N=)
under 17	19.3 (438)	18.7 (445)
18----64	51.0 (1159)	38.5 (916)
65 yrs. and older	29.6 (673)	42.7 (1016)
Age not reported	0.1 (2)	0.1 (2)
TOTAL DEEMED ABLE TO GO HOME (of those in the hospital)	13.0 (258)*	34.2 (813)
under 17	16.8 (62)*	28.9 (129)
18----64	14.6 (155)*	36.6 (335)
65 yrs. and older	16.5 (26)*	34.3 (349)
Age not reported	(15)*	
TOTAL VAIs AT HOME	Not reported	1279
under 17	---	19.2 (245)
18----64	---	61.5 (787)
65 yrs. and older	---	17.2 (220)
Age not reported	---	2.1 (27)
TOTAL VAIs - OTHER PLACE	Not reported	113
MEAN DAILY HOSP COST	\$ 742	\$ 824
TOTAL ANNUAL COST	\$270,830	\$300,760
MEAN MONTHLY HOME COST	\$1776	\$1853
TOTAL ANNUAL COST	\$21,312	\$22,236
NUMBER OF INSTITUTIONS ON WHICH DATA ARE BASED	106**	422***

* TOTAL VENTILATOR DEPENDENT INDIVIDUALS IN 20 STATES
(EXCLUDING PENNSYLVANIA)-1992 VAIs; PERCENTAGES OF PERSONS DEEMED
ABLE TO GO HOME FROM AART REPORT (p.31, AART TIMES Vol.8, 4, 1984)

** HOSPITALS ONLY.

***INCLUDES HOME CARE AGENCIES.

Methodology

In 1983, the AART attempted to identify the number of ventilator assisted individuals in hospitals unable to go home because of reimbursement regulations. After an extensive but fruitless literature search, the association undertook a nationwide survey to determine how many of these patients there were.

The directors of each state society for respiratory therapy were asked to: 1) identify the ventilator assisted individuals in institutions in their state; 2) subdivide these by age; 3) determine the number of long-term ventilator patients who were medically able to receive appropriate care at home; 4) identify costs of institutional care and appropriate home care (Appendix A). Each data collector was contacted to assure consistency of methodology. These data were summarized by a professional statistician and the results were published in the AART Times in April, 1984 (See "The AART makes the 6 o'clock news," AART Times Vol. 8, 4, 28-31, 1984).

In July 1985, Sam Giordano, Executive Director of The American Association of Respiratory Therapists, agreed to repeat their 1983 survey with additions to provide further data on the ventilator population (Appendix A). The directors for AART in each state were asked to contact a minimum of ten institutions in their state to determine: 1) the number of VAIs in the institutions; 2) the age of these patients; 3) how many VAIs were at home; 4) their ages; 5) the costs of institutional care for VAIs; and 6) the costs of home care for VAIs. These

questionnaires were returned to Mr. Giordano by the end of July, and then sent to the Center for Health Administration Studies at The University of Chicago to analyze.

Results

The results of the 1983 and 1985 surveys are summarized in Table 1. In 1985, thirty-seven states (74% of the 50 states) returned reports compared to 21 (42%) in 1983. There were 15 states that were included in both surveys (See State Lists-Appendix B). The total VAIs reported as hospitalized was 2272 in 1983 and in 1985, 2379. In both surveys, the AART researchers identified those patients deemed medically able to go home if reimbursement were possible. The 1985 survey noted that 813 could go home with the highest percentage of patients in the 18-64 age group. The 65 and older had the largest number (349) able to go home if such funding were available. Hospital costs for care of VAIs was reported at an annual cost of 270,830 in 1983 and \$300,760 in 1985. The average monthly home care cost was \$1776 in 1983 and \$1853 in 1985. Both studies support the premise that health care costs could be reduced substantially if those medically able to go home would be discharged to home care. In 1983, the savings were projected as \$249,518 per patient annually and in 1985, this amount could be as high as \$278,524 per patient.

The institutions on which data were based increased from 106 to 422. However in 1985, some home agencies were sampled in addition to the hospitals surveyed in the 1983 survey.

In Table 2, the VAIs 65 and older are sorted by region and rates per 100,000 elderly in those regions are given. If the

probability of being placed on a ventilator was no different by region then its prevalence should rise with increased numbers of persons 65 and over and decrease with lower numbers of persons 65 and older. Table 2 however casts some doubts on this assumption. Although the Middle Atlantic Region has the largest number of people 65 and over and has the second highest rate (9.3), the Mountain Region with the fewest persons 65 and over has the highest rate (11.6). The number of VAIs for the Mountain Region principally reflects estimates for the state of Arizona, long famous for the beneficial effect of its dry climate on respiratory disease and the resultant attraction of individuals with such ailments to that state. The Middle Atlantic Region, in addition to having a large elderly population, also has several medical centers specializing in the treatment of conditions requiring ventilator assistance. The same is true for New England Region as Boston is well-known for the respiratory center at Boston University. The high number of VAIs in South Carolina contributes greatly to the high rate in the South Atlantic Region, as does this region's large number of elderly.

TABLE 2.

NATIONAL DATA INVENTORY
AART SURVEY OF VENTILATOR ASSISTED INDIVIDUALS
Ventilator Assisted Individuals 65 and Over by Region, 1985

REGION (N=STATES)	POPULATION (65+) (000)	VAIs (65+)	RATE PER 100,000 65+
EAST S CENTRAL (4)	1,757	77	4.4
MOUNTAIN (2)	449	52	11.6
WEST S CENTRAL (3)	1,722	28	1.6
PACIFIC (3)	3,423	76	2.2
NEW ENGLAND (5)	1,469	101	6.9
SOUTH ATLANTIC (6)	4,168	330	7.9
EAST N CENTRAL (4)	3,457	42	1.2
WEST N CENTRAL (7)	2,298	87	3.8
MIDDLE ATLANTIC (3)	4,784	443	9.3
TOTAL REGIONS (37)	23,527	1236	5.3

Conclusions

Since only 15 of the 1983 states are represented in the 1985 data, and the reliability of the estimates provided for these 15 states is questionable (based on a careful scrutiny of the raw data), few reliable generalizable interpretations can be made of differences between the two time periods. One could suggest that those states included have fewer VAIs, that there are fewer VAIs than 1983 or that the hospitals that were sampled do not have many VAIs.

In some states the directions accompanying the questionnaire were misinterpreted and estimates of VAIs were used rather than actual numbers reported by sampled hospitals. Some respondents sampled home care agencies to determine the numbers of VAIs at home and some did not. The wide range reported in the cost data may indicate that what was included in these sums may have differed from state to state.

According to the 1985 data, the largest numbers who could home if reimbursement was available are in the oldest group. Although it would seem financially prudent for the passage of a consistent home reimbursement policy, other considerations other than medical criteria may need to be considered before these patients are discharged, however, extensive discharge planning is necessary to ensure a safe and beneficial environment for the ventilator patient. Even if reimbursement is mandated, assurances must be made that all necessary services are available in the patient's home community. It is not easy to create a miniature ICU in a home without qualified service providers, adequate and safe space in the home, frequent follow-up and

perhaps most important, a willing family.

Although the AART study had some limitations as noted above, it does have value in that it is the only national data available on VAIs and provides an overview on a national scope from the perspective of an important group of ancillary professionals serving this population.

NATIONAL ORGANIZATIONS*

Introduction

A list of relevant key informant national institutions (see Appendix C) was compiled by the research team. These organizations deal with the elderly and/or patients with respiratory problems. The purpose of contacting these institutions was to determine who collected information about this population, what type of data was collected, and would it be accessible for use in this study or subsequent ones.

Methodology

The form in Appendix D includes the protocol used for data collection with these institutions. A telephone call was made to each institution, a key individual was identified who was knowledgeable about the data base, and then the National Data Inventory form was administered.

Results

The results of these contacts are summarized in Table 3: The National Data Inventory, National Organizations, Key Informant Organizations Response Rate Profile. The majority of organizations did not collect any data at all on this specific population, but many provided the names of other organizations to

* This section was principally prepared by Susen N. Dunmire, M.A., Research Project Assistant. The author gratefully acknowledges the information provided by Ann Koterla, M.B.A., Consultant to the OTA project, the Chicago Lung Association, and Howard Robboy, Ph.D., Trenton State College, New Jersey, Candice Clark, Ph.D., Montclair State College, New Jersey, and Bernard Goldstein, Ph.D., Rutgers University, New Jersey.

Contract 533-4935.0

contact. One professional organization, the American Academy of Family Physicians, could survey the state through its state family physician network, given three to four months. The family physicians would be able to report on VAIs 65 and older in their practices. The National Center for Health Statistics had diagnosis information, but not specific to VAIs 65 and older. Their data are categorized by DRG codes. There is no DRG code for ventilator patients and there are a variety of DRG codes that may lead to being ventilator assisted. A few organizations, namely The Visiting Nurses Association, Lifecare, Inc., Aamed, and American Abbey Home Care do have diagnosis, ventilator length of stay (VLOS), number of hours per day on the ventilator (VHRS) and source of payment information. There are two problems in obtaining this information: 1) they require a letter describing the study and how the information will be used, as well as a confidentiality statement; and 2) the time frame to retrieve the information ranges from one to three months. We have received a confidential summary of data on VAIs served by one DME vendor.

Conclusions

A national data inventory of key informant organizations revealed that few organizations are collecting data on the ventilator assisted elderly. There may be several reasons why they are not collecting data: 1) this specific population is not large enough to encourage interest in a full-scale study; 2) there are barriers to data collection, such as a lack of access to hospital records; 3) the way data are currently indexed does not provide for the collection and categorizing of data on VAIs in particular.

Contract 533-4935.0

As is evident in the next section dealing with the regional institutions, hospitals are most likely to have the most complete information about this patient population. If a link between patient records in the hospital and the data collection departments in the national institutions could be established, then we could begin to have a clearer sense of this population nationally, the financial and health burdens on the VAI patients and his/her family and the moral and ethical questions to be dealt with in serving this population. Hopefully this greater understanding will lead to solutions to the problem of the cost and type of delivery of health services to this group.

TABLE 3.

NATIONAL DATA INVENTORY
NATIONAL ORGANIZATIONS
Key Informant Organizations Response Rate Profile

Interview Have data Other Organizations
Date on VAIs >65?

Acute (Critical) Care Associations (Respiratory Care Orientation)

American Academy of 8/14 No
Family Physicians*

American Association of (See Part I.: National Data Inventory, AART
Respiratory Therapists Survey of Ventilator Assisted Individuals:
Comparison of 1983 and 1985 Surveys)

American College of 8/14 No Glassrock
Chest Physicians Baxter Travenol
Linde Home Division

American Medical 8/20 No National Center for Health Statistics
Association* AART

American Nurses' 8/14 No Critical Care Nursing
Association, Inc. American Assoc. of Neuroscience Nurses

American Occupational 8/15 No AART
Therapy Association

American Physical 8/21 No University of New England, Geriatrics,
Therapy Association Cardio-Pulmonary Dept.

Critical Care Society 8/14 No

National Institutes of 8/14 No National Academy of Sciences
Health

Visiting Nurses Assoc.* 8/23 Yes

Pertinent Disease-Oriented Associations

ALS Association, Inc. 8/22 No Self-help group at Mt. Sinai Hospital

American Cancer Society 9/9 No

American Lung Assoc. 8/22 No

TABLE 3. (continued)

Interview Data on Date		VAIs >65?	Other Organizations
National Foundation for Long Term Health Care	9/9	No	
Polio Information Center	8/23	No	No self-help group or other groups in N.Y.
Respicare*	8/23	No	Americare
<u>Organizations dealing with the elderly</u>			
Administration on Aging	9/9	No	
American Aging Assoc.	8/14	No	National Heart Assoc. NIH National Heart & Lung ventilator manufacturers American College of Physicians VA
American Association for International Aging	9/9	No	Foundation for Long Term Care
American Association of Homes for the Aging	9/9	No	
American Federation for Aging Research	8/22	No	
American Geriatrics Society	8/22	No	
American Longevity Association	8/14	No	National Institute on Aging
Federal Council on Aging	9/9	No	
Lifecare, Inc.*	8/28	Yes	
National Academy of Sciences*	9/6	Yes	
National Geriatrics Society	8/14	No	Gerontological Society
National Council on the Aging	9/9	No	
Rehabilitation Engineering Program*	8/20	No	Office of Aging

TABLE 3. (continued)

Interview Date	Data on VAIs >65?	Other Organizations	
<u>Organizations dealing with health care institutions</u>			
American College of Health Care Administrators	8/15	No	American Health Care Association American Association of Homes for the Aging
Commission on Professional Hospital Activities*	9/3	Yes	
HCFA*	8/28	Yes	
Illinois Assoc. of Rehabilitation Facilities	8/21	No	Member Organizations
Joint Commission on Accreditation of Hospitals	8/19	No	
National Center for Health Services Research	8/23	No	HCFA
National Center for Health Statistics*	8/15	No	
Veterans Administration* (North Chicago)	8/22	No	
Veterans Administration Washington, D.C.	9/16	No	
<u>Home Care Associations</u>			
American Continuity of Care	8/28	No	
American Federation of Home Health Agencies	9/9	No	
Illinois Continuity of Care Organization*	8/28	No	
National Association for Home Care	9/9	No	
National Foundation for Hospice and Home Care	9/9	No	

TABLE 3. (continued)

	Interview Date	Date on VAIs >65?	Other Organizations
<u>Related Trade Association</u>			
Manufacturers and Suppliers:			
DME vendors			
Glassrock Home Care*	8/29	No	
Travenol*	8/22	Yes	
Foster Medical*	8/23	Yes	Abbey Medical Amed Oak Forest Hospital
<u>Home Health Care Providers</u>			
Amed*	8/23	Yes	Homecare Associates
American Abbey Home Care*	8/23	Yes	Foster Travenol Amed
HomeCare Associates, LTD.*	8/20	No	Goldwater Hospital Nursing Agencies DME Vendors Lifecare Access Living
Upjohn	8/23	No	
Quality Care*	8/23	Yes	AART study St. Mary's, Milwaukee Rancho Los Amigos Study, 1973-79 Loma Linda Home Care Cleveland Clinic
<u>Financial Organizations</u>			
Department of Health and Human Services, HCFA	8/28	No	Office administrators, Medicare and Medicaid
Health Insurance Association of America*	8/22	No	
Health Insurance Council of America	8/28	No	

TABLE 3. (continued)

	Interview Date	Data on VAIs >65?	Other Organizations
Illinois Department of Rehabilitation Services	8/21	No	Department on Aging Public Health Department of Health Planning
Illinois Department of Public Aid*	8/28	No	Americare

* Additional information available. Citations follow.

American Academy of Family Physicians

Question 2:

Kind of information?

If they had more time, they could survey the state by state family physician network to establish how many ventilator assisted individuals there are 65 and over.

American Medical Association

Question 2:

Kind of information?

Do not have any patient data.

Visiting Nurses Association

Questions 6 & 7:

Have 2 VAIs>65:

1. Diagnosis: COPD, cardiac and Hypertension, COPD
VLOS: none, at home
VHRS: 24
EVLOS: 24
Payment sources: Unknown
2. Diagnosis: ALS, Hypertension, ALS
VLOS: none, at home
VHRS: 24
EVLOS: 24
Payment sources: Unknown

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Transportation
2. Money
3. Help at home

TABLE 3. (continued)

Respicare

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. HCFA's guidelines that allow elderly to not be responsible for 20% of co-insurance.

2. Financial burden elderly must assume because they're booted out of hospitals.

Lifecare, Inc.

Questions 2 & 3:

Requirements to obtain data from files?

Write a letter and request information Would take 2-3 weeks.

Questions 5 & 6:

Have identified 1500 VAIs ranging in age from 6 months to 97 years.

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

Concern of the elderly that they cannot get funding for care in the home.

National Academy of Sciences

The Panel on Statistics for an Aging Population

Question 2:

The following sources may provide relevant information. The inventory of data sets is currently being indexed. Bernard Goldstein, Ph.D. searched through the files to ascertain relevant sources.

National Survey of the Aged 1975. Sample was total U.S. noninstitutional population age 65 and over. Includes degree of health and use of health services. Publication: Ethel Shanas, National Survey of the Aged 1975. DHS Pub No. (OHDS) 83-20425 1983. Data tape: National Archive of Computerized Data on Aging, Interuniversity Consortium for Political and Social Research, Ann Arbor.

Title: National Survey of Long-term Care/National Survey of Caregivers

Sponsor: Asst. Secretary for Planning and Evaluation and Health Care Financing Administration

Project Director: Paul D. Gayer, Economist, Division of Long Term Care Policy, Office of Social Services Policy, ASPE/SSP DHHS D.C.

Purpose: To provide information on the noninstitutional population over 65 needing assistance with daily living and their caregivers.

Design: National sample of population 65 and over, screened for long-term dependency. Second wave currently underway. Interview with about 2,000 unpaid voluntary caregivers who provide assistance to the dependent elderly who were interviewed.

Year of Data Collection: 1982 and 1984

Unpublished data to be available Summer, 1985

Contact: Paul D. Gayer (202) 245-6613

TABLE 3. (continued)

Title: Survey of Income and Program Participation (SIPP)
Sponsor: Bureau of Census, Department of Commerce
Project Director: Roger A. Herriot, Chief, Population Division, Bureau of
Census
Purpose: Has data on chronic limitations
Contact: Customer Services, Data Users Services Division, Bureau of Census
(301) 763-4100

Title: Durham Old Age Resources and Services Community Survey
Sponsor: Duke University, Center for the Study of Aging and Human
Development
Year of Data Collection: 1972-73 with follow-up in 1974-75
Contact: Linda K. George, Ph.D., Director, Data Archive for Aging Adult
Development
Box 3003
Duke University Medical Center
Durham, N.C. 27710
(919) 684-3204

Title: The National Health Care Expenditures Survey, 1977-78
Sponsor: National Center for Health Services Research and Health Care
Technology Assessment, and National Center for Health Statistics
Project Director: Daniel G. Walden, Ph.D., Senior Research Manager
Division of Intramural Research, NCHSR
350 Park Building, 5600 Fishers Lane
Rockville, MD 20857
Purpose: To provide a comprehensive statistical picture of how health
services are used and paid for in U.S.
Year of Data Collection: Six rounds in 1977-78. Plan another in 1987.
Tapes are available.
Contact: Daniel Walden, (301) 443-4836

Title: National Health Interview Survey
Sponsor: National Center for Health Statistics
Project Director: Stewart C. Rice, Jr., Chief, Survey Planning and
Development Branch, Division of Health Interview
Statistics, NCHS
3700 East-West Highway, Hyattsville, MD
Purpose: To provide data on the incidence of acute conditions, limitations
of activity...hospitalization, disability days...prevalence of
selected chronic conditions
Design: A continuing nationwide household interview survey.
Publications: Current estimates
Contact: Robert Fuchaberg
(301) 436-7084

TABLE 3. (continued)

Title: Second National Health and Nutrition Examination Survey
 Sponsor: National Center for Health Statistics
 Project Director: Robert S. Murphy, Director, Division of Health
 Examination Statistics
 Center Building, Room 2-58
 NCHS 3700 East-West Highway
 Hyattsville, MD 20782
 Contact: Patricia A. Vaive (301)436-7080

Title: 1980 National Medical Care Utilization and Expenditures Survey
 Sponsor: National Center for Health Statistics Health Care Finance Admin.
 Update Study: Planned for 1987
 Publications: National Medical Care Utilization and Expenditures Survey Data
 Report Series. Public tapes - NTIS, Interuniversity Consortium
 Contact: Robert A. Wright, Project Director, Chief, Utilization
 Expenditures Statistics Division of Health Interview Statistics,
 NCHS
 (301) 436-7100

Title: Survey of Aging Veterans
 Sponsor: Veterans Administration
 Project Director: Robert S. Feitz, Statistician, Respiratory Division
 VA, 810 Vermont Ave.

Purpose: Survey yields baseline data on health status, on noninstitutional
 veterans, 54 and over.
 Contact: Feitz
 (202) 389-3052

Rehabilitation Engineering Program

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical
 ventilation?

1. Concern for those who should be on, can be, but aren't.
2. Prolonging life.
3. Will individuals be able to afford it? If not, will government be
 sensitive to right to life? Don't forget people want to live.
4. Don't think people have choices-only hospital and nursing home.
5. Improper education for families and caregivers.
6. Haven't investigated congregate housing.
7. Insurance companies have not investigated less expensive alternatives.
8. Approaching ill people and asking them to make decisions.

TABLE 3. (continued)

Commission on Professional Hospital Activities

Question 2:

Kind of information?

They do have diagnosis and source of payment information that they can compile from the Medical Records Abstract of 20 hospitals. They could identify the range of patients 65 and older with certain diagnosis in particular hospitals. Contacts could then be made with the hospital to obtain VLOS, VHRS, and EVLOS.

Health Care Financing Administration, Bureau of Data Management and Strategy

Question 2:

Kind of information?

They have data on patients who are recipients of Medicare in a procedure code file. The files include nationwide data, but they can access particular localities. A 5% beneficiary file includes data on 5% of the population, demographic characteristics, diagnosis, services received and the cost of specific services and equipment.

National Center for Health Statistics

Question 2:

Kind of information?

They do have diagnosis information, but not specific to ventilator assisted individuals 65 and older.

Veterans Administration (North Chicago)

Questions 5 & 6:

Survey as of April 1984, 244 patients >65 in 171 hospitals. Mostly men.

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Funding
2. Relief for the wife while she's out can be difficult.

TABLE 3. (continued)

Illinois Continuity of Care Organization

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Family support
2. Financial
3. Resources in community
4. Rural setting difficult for resources.

Glassrock Home Care

Questions 2 & 4:

Kind of information, number of VAIs 65 and over and source of payment?

Most of their patients are <65. They would guess that the number of their patients 65 and older would be no more than 1.0%. The cost for equipment ranges from \$600 to \$1200. 20% is paid for by the patient, and 80% by Medicare.

Travenol

Questions 2-7:

Kind of information?

Received a confidential summary of information regarding their ventilator patients.

Foster Medical

Questions 3 & 4:

Requirements to obtain these data?

Authorization. Would receive information the same day.

Question 5:

Number of VAIs identified?

40%

Question 6:

Number of VAIs 65 and older?

60%

Question 7:

Diagnosis: 50% with ALS; 50% with failure of diaphragmatic pacers.
Payment sources: Medicaid and Private insurance.

TABLE 3. (continued).

Aimed

Question 7:

Info: Have one patient. Calls once a month, checks ventilator and supplies oxygen. Can't provide diagnosis, days and hours on ventilator or payment source information.

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Who will care for the individual?
2. Cost.

American Abbey Home Care

Question 5 & 6:

Number of VAIs: 100

Number that are 65 and older: The majority of the total number of VAIs

Question 3 & 4:

Requirements to obtain data:

Approval from corporate vice-president. Would take a couple of weeks.

Question 7:

Age: The majority of patients are 65 or older.

Some diagnoses: ALS, COPD, Cerebral Palsy, Multiple Sclerosis.

Unit: Home

VLOS: Some every day

VHRS: Not sure

EVLOS: Not expected off

Payment sources: Medicare, Medicaid, Private Insurance, some Public Aid

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Family/community support
2. Support services
3. Payment-could process be smoothed out?
4. Services and supplies smoothed out?
5. Lung Association should do follow up project.

TABLE 3. (continued)

HomeCare Associates, LTD.

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. To have another person to assist-difficult.
2. Funding-difficult. Also why are they home? Look at reasons. Are they home because they want to be or are they pushed out?
3. Doesn't see adults out with the kind of support they'd been able to obtain for children.
4. Quality of life.
5. Some people should not be kept alive and they are.

Quality Care

Question 3:

Requirements to obtain data:

Contact the office and have them conduct a survey of 170 offices.

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

1. Are we providing quality of life for the patient?
2. Is the home care cost and care effective? We see home care as most cost effective.
3. Acceptability of the home.
4. Ethical issue--is this best for patient and family?

Health Insurance Association of America

Question 2:

Kind of information?

In terms of insurance reimbursement, they have information from HCFA and Medicare.

Illinois Department of Public Aid

Question 8:

Major issues in caring for an elderly individual on prolonged mechanical ventilation?

Clearer definition of the population to deal with negotiated rate in nursing homes. They're backed up in hospitals.

PART II*

REGIONAL INSTITUTIONS CASE STUDIES

Introduction

Ten key institutions representing seven regions in the United States plus one institution in Canada were identified as leaders in caring for ventilator patients in their respective areas. Data were collected from these institutions on the age distribution, diagnoses, number of days and number of hours per day on the ventilator, the expected length of stay on the ventilator, the source of payment, average cost and the definition of prolonged mechanical assistance and trends in the numbers of VAIs they served. The data provided by these organizations permits an opportunity to examine regional variation in the numbers and kinds of VAIs treated in different parts of the country and thereby provides another "look" at this population from the perspective of some of the major regional centers actually serving them.

Methodology

Dr. Allen Goldberg, with input from the Office of Technology Assessment, provided CHAS the names of institutions and individuals who were extensively involved in the treatment of ventilator assisted individuals. The list of these institutions

*This section was principally prepared by Susan N. Dunmire, M.A., Research Project Assistant. The author gratefully acknowledges the information provided by participating institutions (listed in Appendix E).

is provided in Appendix E. An initial telephone call was made to each institution to elicit participation in the study. The contact person at each site was asked if he/she collected data or would be able to collect data on ventilator assisted individuals age 65 and over. If the respondent answered yes, a regional data inventory (Appendix F) was sent to them to complete. If the respondent answered no, no inventory was sent. Of the eleven institutions contacted, ten data inventories were sent (one institution indicated that they had no VAIs 65 and older), and all of these were completed and returned to CHAS. (Two were returned after the preliminary report was submitted. Their data are incorporated in this final report.)

Follow-up phone calls were made to the institutions five days after the inventories were mailed to confirm they were received, and to answer any questions regarding the inventory. Periodic phone calls were made until the completed inventories were received. Upon receipt of the inventory, unclear data were clarified in a phone call to the key informant.

All patient data are included for those individuals 65 and over who required mechanical ventilation at least four hours per day over at least a two week time period. Data from three patients who were on a ventilator less than 14 days, one for 10 days and two for 13 days were included because they were expected to remain on the ventilator for at least four more days, which would qualify them as requiring prolonged mechanical ventilation.

Two key informant^s contributed additional information from studies they have conducted (See Appendix G and H). One other informant mentioned data presently being tabulated on VAIs in his institution, which may be available in a few months.

Findings

Table 4 lists the 46 patients from the seven census regions from which data were received. Their age, diagnoses, unit, number of days on the ventilator (VLOS), number of hours per day on the ventilator (VHRS), expected length of time on the ventilator (EVLOS) and payment source information are included. These data are summarized in Table 5.

Age and Diagnosis

Table 5 summarizes the data in Table 4. In Table 5, eight of the ten reporting institutions listed VAIs 65 and older, with a total number of 46 patients. These VAIs ranged in age from 65 - 84, with 72 as the mean age. Diagnoses are listed according to the primary, and secondary diagnoses and the diagnosis leading to the patient being ventilator assisted. The primary diagnoses are clustered around neurological/neuromuscular (37.0%) and respiratory (45.7%) diagnoses. Respiratory diagnoses comprise close to half (48.6%) of the secondary diagnoses. The category 'other', has the second greatest percentage of diagnoses at 31.4%. The diagnoses most commonly leading to the individual being ventilator assisted are respiratory, at 48.7%.

VLOS, VHRS, and EVLOS

As for time spent on the ventilator, over half of the patients (69.4%) were on the ventilator for six months or less.

Only 27.8% of the patients were on the ventilator longer than a year. Over ninety-five percent (95.3%) were on the ventilator for 12 hours or more a day, with 76.7% of the total number of the patients on the ventilator for 24 hours. The answers to the expected additional time the patient would need to be on a ventilator varied, but the greatest percentages were in the categories of lifetime and until death, totaling 80.5%.

Cost

The payment source information reveals that Medicare and Medicaid cover the greatest percentage of the cost of a VAI's care. Thirty two patients out of 40 had 76 - 100% of the cost covered by Medicare or Medicaid. Two patient's private insurance covered 76 - 100% of the cost, and three patients had other sources which paid 76 - 100%. The rest of the patients had a combination of payment sources.

Other Issues

Table 6 provides a summary of the responses to questions 5 through 9 on the data inventory (see Appendix F).

Cost. There is a wide range (\$110 - 2286) in the approximate cost billed per day per VAI in a particular system. The variance in this range could be attributed to the varying costs assigned to the different care units within an institution and across various institutions. The mean cost reported was \$938.13.

VAIs: Increase, decrease or stay the same? In the past month, 90.0% of the respondents reported that the number of VAIs 65 and over have stayed the same. Projecting into the next six months, 30.0% of the responding institutions expected to see an

increase in the number of VAIs. The explanations cited for the number of VAIs increasing can be categorized as specific to the type of institution and the presence of a unit for VAIs at that institution. Facilities with specialized units for VAIs, such as an academic institution, expect to see an increase because other institutions recognize their expertise. In addition, more patients are being transferred to their institution because of the DRG reimbursement mechanism. The fact that they have appropriate chronic care facilities and that other acute care institutions lack sufficient funding are the two main reasons certain types of institutions expect an increase in the number of ventilator assisted patients.

One responding institution expected to see a decrease in the number of VAIs in the next six months. The explanation given was that more patients, particularly the elderly with terminal diseases, are being treated as 'No code'. Patients and/or their families are deciding that they should not be placed on a ventilator.

Over half (60.0%) of the responding institutions expected the numbers of VAIs to stay the same in the next six months. The explanations were based mainly on their experience to date. Their numbers of VAIs age 65 and over have remained approximately the same over the past few years, and they do not expect any dramatic increases in the next few months.

Opinion: Why place a patient on mechanical ventilation other than for life saving purposes? All of the nine institutions responding agreed that one of the main reasons for placing an elderly patient on a ventilator was to enable the patient to

continue a productive life. Two-thirds (66.7%) of the respondents agreed that a main reason is that the patient has available support persons to care for him/her. Over half (55.6%) agreed that one of the main reasons was that the patient has appropriate coverage or reimbursement. The vast majority (88.9%) of the respondents agreed that one of the main factors considered is that the patient has a reasonable level of mental competence.

A recurring theme in the 'other' responses is placing an elderly patient on the ventilator to reverse the 'primary disease process' to 'overcome apparent worsening of respiratory failure not otherwise reversible'. Several respondents discuss the decision-making process involved in placing an elderly person on a ventilator. Careful consideration of the above mentioned factors is essential by the family and the patient, if he or she is competent. Obtaining informed consent from the patient is repeatedly mentioned as a qualification before the patient is ventilated.

Appropriate definition of "prolonged ventilator dependency".
Responses to this question diverged from the definition used in the data inventory in terms of the time frame. The answers ranged from a patient who is on a ventilator longer than 48 hours for a portion or all of the day, to a patient who is on a ventilator longer than three months. One institution defined a VAI as a patient who is not able to be weaned from the ventilator and/or as a patient who requires ventilation to prevent respiratory failure.

Conclusions

Data from ten institutions in seven regions across the country do not represent the total population of VAIs in the U.S. These data do, however, provide insights into the variability across major institutions in different parts of the country of the actual VAI patients they serve, and the issues involved in the care of these patients. Institutions with special ventilator units are witnessing an increase in the number of patients, in part explained by the existence of such a unit, and in part explained by the DRG reimbursement system in which community hospitals transfer these kinds of patients out since they cannot "afford" to keep them past the maximally-reimbursed length of stay rate. Other institutions record the VAI population remaining the same. Even though the elderly population is growing, the VAI population 65 and over may not be growing because of patient, family or medical team decisions not to ventilate the patient. The main purposes for ventilating an elderly patient are 1) life-saving, 2) to enable the patient to continue a productive life, 3) the patient has a reasonable level of mental competence, 4) patient has available support persons to care for him/her, 5) patient has appropriate coverage or reimbursement, and 6) to reverse the primary disease process.

In order to collect accurate cost data, to arrive at a consensus on the definition of prolonged mechanical ventilation, and to identify the total number of VAIs in the entire country, a representative sample of all institutions providing care to VAIs would be necessary. A data inventory similar to the one in

Appendix F could be administered with more detail requested about the type of institution and the kind of unit and services provided for VAIs. The cost and definition data could then be compared and contrasted among like institutions and units and aggregate estimates developed for the nation as a whole.

TABLE 4.

REGIONAL INSTITUTIONS CASE STUDIES
Data Inventory: Profile of Cases Reported

VAI	AGE	DIAGNOSIS	UNIT	VLOS	VHRS	EVLOS	PAYMENT SOURCES				
				(days)	(hours)	(days)	Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
Region: West North Central (1)											
1	66	a) Ri6 Fx	PRCU	13*	12	7	1	2	3	4	5
		b) Fx Pelvis					(x) 100	(x)	(x)	(x)	(x)
		c) Ri6 Fx									
2	83	a) ALS	PRCU	397	24	Until death	1	2	3	4	5
		b) Pneumonia					(x)	(x)	(x) 100	(x)	(x)
		c) ALS									
3	68	a) CVA	PRCU	38	24	Until death	1	2	3	4	5 HMO Seniors
		b) Central Hypoventilation					(x)	(x)	(x)	(x)	(x) 100
		c) Central Hypoventilation									
4	65	a) Guillian Barre	PRCU	60	20	30	1	2	3	4	5
		b) Respiratory Failure					(x)	(x) 100	(x)	(x)	(x)
		c) Guillian Barre									
5	74	a) ALS	PRCU	90	24	Until death	1	2	3	4	5
		b) Pneumonia					(x)	(x) 100	(x)	(x)	(x)
		c) ALS									
6	67	a) Polio	PRCU	1460	24	Until death	1	2	3	4	5 Patient
		b) Osteoporosis					(x)	(x) 60	(x)	(x)	(x) 20
		c) Polio									
Region: New England (2)											
7	66	a) COPD		70	14	Lifetime	1	2	3	4	5
		b) Kyphosis					(x) 14	(x) 86	(x)	(x)	(x)
		c) COPD									
8	72	a) COPD		100	24	Lifetime	1	2	3	4	5
		b) Adenocarcinome of the rectum					(x) 33	(x) 67	(x)	(x)	(x)
		c) COPD									

VAC	AGE	DIAGNOSIS	UNIT	VLOS (days)	VLOS (hours)	ELOS (days)	PAYMENT SOURCES						
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)		
9	77	a) COPD		58		12	Lifetime	1	2	3	4	5	
		b) Sigmoid diverticulosis											
		c) COPD						(x) 100	(x)	(x)	(x)	(x)	
10	79	a) COPD		2277		24	Lifetime	1	2	3	4	5	
		b) Muscle wasting											
		c) COPD						(x)	(x) 100	(x)	(x)	(x)	
11	66	a) Post polio syndrome		113		8	Lifetime	1	2	3	4	5	
		b) Kyphoscoliosis											
		c) COPD						(x)	(x) 75	(x) 25	(x)	(x)	
12	74	a) COPD		13*		8	Lifetime	1	2	3	4	5	
		b) Duodenal ulcer											
		c) COPD						(x) 100	(x)	(x)	(x)	(x)	
13	71	a) COPD		174		24	Lifetime	1	2	3	4	5	
		b) Malnutrition											
		c) COPD						(x) 50	(x)	(x) 50	(x)	(x)	
14	81	a) Kyphoscoliosis		27		24	More than 2 months	1	2	3	4	5	
		b) Superimposed Pneumonia											
		c)						(x) 100	(x)	(x)	(x)	(x)	
Region: Canada (1)													
15	76	a) COPD		ICU		18	12	14	1	2	3	4	5_OHIP**
		b) Pneumonia											
		c) Pneumonia							(x)	(x)	(x)	(x)	(x) 100
16	74	a) Aortic		ICU		87	12	3	1	2	3	4	5_OHIP**
		dissection											
		b)							(x)	(x)	(x)	(x)	(x) 100
		c) Aortic dissection											
Region: South Atlantic (1)													
17	65	a) Aortic		NA*		NA*	NA*	NA*	1	2	3	4	5
		b) COPD, CAD											
		c) CAD and COPD							(x) 99	(x)	(x) 81	(x)	(x)

VAI	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
<u>Region: East North Central (1)</u>											
18	65	a) Parkinsons	ICU	21	24	4	1	2	3	4	5
		b)					(X) X	(X)	(X) X	(X)	(X)
		c) Respiratory Failure									
19	74	a) Respiratory	ICU	18	24	Life	1	2	3	4	5
		distress					(X) X	(X)	(X) X	(X)	(X)
		b)									
		c) Respiratory distress									
20	65	a) Aortic	ICU	26	24	Life	1	2	3	4	5
		Aneurysm					(X) X	(X)	(X) X	(X)	(X)
		b)									
		c) Respiratory failure									
21	79	a) ARDS	ICU	32	24	Life	1	2	3	4	5
		b)					(X) X	(X)	(X) X	(X)	(X)
		c) ARDS									
22	69	a) Congestive	ICU	18	24	?	1	2	3	4	5
		heart failure					(X) X	(X)	(X) X	(X)	(X)
		b)									
		c) Respiratory failure									
23	79	a) Polyneuropathy	ICU	10	12	5	1	2	3	4	5
		b) Respiratory failure					(X) X	(X)	(X) X	(X)	(X)
		c) Respiratory failure									
<u>Region: Middle Atlantic (1)</u>											
24	67	a) COPD Emph	D22			24 lifetime	1	2	3	4	5
		b) Childhood Asthma					(X)	(X) +	(X)	(X)	(X)
		c) Cor Pulmonale									
25	70	a) s/p CPR	D22			24 lifetime	1	2	3	4	5
		b) Recurrent pneumonia					(X)	(X) +	(X)	(X)	(X)
		c) Down Syndrome									
26	66	a) COPD	D22			24 lifetime	1	2	3	4	5
		b) ASHD					(X)	(X) +	(X)	(X)	(X)
		c)									

VAI	AGE	DIAGNOSIS	UNIT	VLDS (days)	VARS (hours)	SVLDS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
27	71	a) COPD	D22			24_lifetme	1	2	3	4	5
		b) Rec Pneumonia					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
28	83	a) COPD	D22			24_lifetme	1	2	3	4	5
		b) Bronchiectasis					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
29	78	a) Multiple CVA	D22			24_lifetme	1	2	3	4	5
		b) s/o CPR					(%)	(%)_+++	(%)	(%)	(%)
		c) Metastatic lung disease									
30	72	a) COPD Emph	D22			24_lifetme	1	2	3	4	5
		b) s/o Thoracoplasty for TB					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
31	78	a) Rheumatid Lung	D22			24_lifetme	1	2	3	4	5
		b) Rec. Pneumonia					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
32	65	a) COPD	D22			24_lifetme	1	2	3	4	5
		b) Cor pulmonale					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
33	82	a) COPD	PCU	43		24_lifetme	1	2	3	4	5
		b) Cor pulmonale					(%)	(%)_+++	(%)	(%)	(%)
		c) _____									
34	84	a) COPD	PCU	70		24_lifetme	1	2	3	4	5
		b) Cardionypathy					(%)	(%)_+++	(%)	(%)	(%)
		c) Hypoproteineim									
35	74	a) COPD	PCU	34		24_lifetme	1	2	3	4	5
		b) Recurrent pneumonia					(%)	(%)_+++	(%)	(%)	(%)
		c) Cor pulmon prolapsed initral valve									
36	76	a) MI	ICU	62		24_indefinite	1	2	3	4	5
		b) CHF					(%)	(%)_+++	(%)	(%)	(%)
		c) Pulmon Edema									

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VAT	AGE	SYMPTOMS	UNIT	VLOS (days)	VARS (hours)	EVLOS (days)	PAYMENT SOURCES					
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)	
37	66	a) ALS b) Coma c) ALS	Rehab	1072		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
38	65	a) ALS b) Cholelithiasis c) AIS	Rehab	8200		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
39	69	a) Cervical disc herniation b) Anterior spinal cord syndrome c) Cervical disc herniation	Rehab	305		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
40	66	a) ALS b) HTN c) ALS	Rehab	2555		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
41	81	a) ALS-Coma b) CHF c) ALS	Rehab	1825		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
42	69	a) Fascio-Scapula MD b) _____ c) Fascio-Scapula MD	Rehab	459		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
43	69	a) ALS b) Chronic UTI c) ALS	Rehab	66		24	Until death	1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)
44	74	a) Guillian Barre Syndrome b) Hypothyroidism c) Guillian Barre Syndrome	Rehab	130		16	365	1	2	3	4	5
								*(%)	(%)	(%)	(%)	(%)

Region: Pacific (1)

45	76	a) Guillian Barre Syndrome b) _____ c) Guillian Barre Syndrome		1950		?		1	2	3	4	5
								(%)	(%)	(%)	(%)	(%)

Contract 533-4935.0

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PAT	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
46	69	a) COPD		1025		?	1	2	3	4	5
		b)									
		c) COPD					(X)	(X)	(X)	(X)	(X)
		a)					1	2	3	4	5
		b)									
		c)					(X)	(X)	(X)	(X)	(X)
		a)					1	2	3	4	5
		b)									
		c)					(X)	(X)	(X)	(X)	(X)
		a)					1	2	3	4	5
		b)									
		c)					(X)	(X)	(X)	(X)	(X)

* Less than two weeks

** Ontario Health Insurance Plan

*** Benefits exhausted; billing Medicaid

TABLE 5.

REGIONAL INSTITUTIONS CASE STUDIES
Summary Response Rate Profile

Reporting Institutions

Total number: 10

Total number with VAIs 65 and older: 8

VAIs Reported

Total number age 65 and older: 46

Age range: 65-84

Mean age: 72

Diagnoses

	Total	Percent (%)
Primary		
Cardiac complications (ie. CHF, Aortic aneurysm)	6	13.0 %
* Neurological/neuromuscular (ie. ALS, CVA, Polio)	17	37.0
Respiratory (ie. COPD, ARDS, pneumonia)	21	45.7
Other (ie. trauma, G.I. system, cancer)	2	4.3
Total	46	100.0
Secondary		
Cardiac complications (ie. CHF, Aortic aneurysm)	6	17.1
Neurological/neuromuscular (ie. ALS, CVA, Polio)	1	2.9
Respiratory (ie. COPD, ARDS, pneumonia)	17	48.6
Other (ie. trauma, G.I. system, cancer)	11	31.4
Total	35	100.0
Leading to being ventilator assisted		
Cardiac complications (ie. CHF, Aortic aneurysm)	4	10.3
Neurological/neuromuscular (ie. ALS, CVA, Polio)	12	30.8
Respiratory (ie. COPD, ARDS, pneumonia)	19	48.7
Other (ie. trauma, G.I. system, cancer)	4	10.3
Total	39	100.1

TABLE 5. (continued)

Reported Time on a Ventilator

Total Time (VLOS) Range: 10*-8200 days			Hours per Day (VHRS) Range: 8 - 24 hours		
	Total Number	Percent (%)		Total Number	Percent (%)
10 - 13 days	__3*__	__8.3 %	<12 hours	__2__	__4.7 %
14 - 30 days	__6__	__16.7	12 - 23 hours	__8__	__18.6
1 - 3 months	__12__	__33.3	23 - 24 hours	__33__	__76.7
3 - 6 months	__4__	__11.1	Total patients	__43__	100.0
6 - 12 months	__1__	__2.8			
> 12 months	__10__	__27.8			
Total patients	__36__	100.0			

* Please note: Data from three patients are included who were on the ventilator less than our definition time of 14 days.

Expected Additional Time on the Ventilator (EVLOS)

Range: 3 days - Lifetime

	Total Number	Percent (%)
Lifetime	__22__	__53.7 %
Until death	__11__	__26.8_
1 - 5 days	__2__	__4.9_
6 - 14 days	__2__	__4.9_
15 - 30 days	__2__	__4.9_
> 2 months	__2__	__4.9_
Total patients	__41__	100.1_

TABLE 5. (continued)

Payment Sources (Number of VAIs)*

	Medicare	Medicaid	Private Insurance	Family	Other
% of services covered					
<25%	--1--	-----	--2--	-----	--1--
26 - 50%	--1--	-----	--1--	-----	-----
51 - 75%	--1--	--2--	-----	-----	-----
76 - 100%	--6--	--26--	--2--	-----	--3**
Total n	--9--	--28--	--5--	-----	--4--

* Please note: Seven institutions reported data on 40 patients.
More than one payment source may be listed per patient.

** 1 patient has HMO seniors. 2 patients have OHIP: Ontario Health Insurance Plan.

TABLE 6.

REGIONAL INSTITUTIONS CASE STUDIES
Other Issues Regarding Prolonged Mechanical
Ventilation for VAIs*

1. Response to question 5: What is the approximate amount billed per day for the elderly VAIs in your system?

Range of cost (\$) 110** - 2286

Mean cost (\$) __938.13__

Total number of institutions responding __8__

2. Response to question 6: In the past month have the numbers of VAIs in your system 65 and over, increased?... decreased?... or stayed about the same?

	Total Number	Percent (%)
Increased	___1__	_10.0_ %
Decreased	___0__	_0.0_
Stayed about the same	___9__	_90.0_
Total	__10__	100.0

3. Response to question 7: Do you think that in the next six months the number of VAIs in your system 65 and over, will increase?... decrease?... or stay about the same?

	Total Number	Percent (%)
Increase	___3__	_30.0_ %
Decrease	___1__	_10.0_
Stay about the same	___6__	_60.0_
Total	__10__	100.0

TABLE 6. (continued)

Explanations:

Increase

1. Yes, waiting list for ventilator patients - capacity to be increased.
2. I would expect them to increase for neuromuscular diseases if funding becomes insufficient and if chronic care facilities are developed to care for patients. Appropriate chronic care facilities are real key.
3. Since we are an academic health center with a specific program for ventilator dependent patients we expect to continue to receive this more complex patient population. Another factor contributing to the transfer of these patients to our institution is the DRG reimbursement system, so that community hospitals throughout our state tend to transfer these patients more readily than they had in the past.

Decrease

1. More patients are being treated as "No Code" - especially elderly with terminal diseases.

Stay about the same

1. Six months is too short a time to see any trends.
2. In reviewing the applications we are currently receiving this opinion is reinforced.
3. 1983 - 84 data show 1,065 ICU admissions of which 249 patients aged 65 - 75 and 58 patients aged >75; therefore, 307/1065 patients aged > 65. Future selection factors will not change suddenly over six month period.
4. The number of VAIs fluctuate as do the number over 64 years of age. However, we have seen no increase over the past few years and anticipate no increase in the future.
5. Most of the VAIs have neuromuscular problems. These individuals tend to be younger than 65.

TABLE 6 (continued)

5. Three separate opinions were submitted from one institution. Two opinions were, 'stayed about the same', with the following explanation: most of our patients are chronic long term, so turnover is relatively slow. One opinion was, 'an increase was expected', with the following explanation: the winter months are the months of exacerbation of respiratory failure in COPD patients due to pneumonia, URI, flu, etc...There is a long waiting list for our facility for patients hospitalized on ventilators at present, in both acute and university hospitals in our area.
4. Response to question 8: In your opinion, what are the main reasons for placing an elderly person on a ventilator other than for life-saving purposes? (The respondent was asked to circle ALL THAT APPLY. Therefore, one institution may have chosen several or all of the given answers, and the percentages may not total 100%.)

Total institutions responding: 9

	Total Number of Responses	Percent (%)
a. enable patient to continue a productive life	__9__	__100.0_ %
b. patient has available support persons to care for him/her	__6__	__66.7_
c. patient has appropriate coverage or reimbursement	__5__	__55.6_
d. patient has a reasonable level of mental competence	__8__	__88.9_
e. other (explanations listed)		
1. See "Guidelines for Care of Ventilator Patients" by ACCP.	__1__	__11.1_
2. Patient has a reasonable chance of overcoming the problem and/or the patient is willing to accept the possibility of lifelong mechanical assistance. Patients on external ventilators should constitute a separate category since this is a readily changeable situation not requiring intubation.	__1__	__11.1_

TABLE 6. (continued)

3. To overcome apparent worsening of respiratory failure not otherwise reversible. (When prolonged ventilator dependency appears probable: then informed consent should be obtained from the patient that he wishes to continue life even if as a ventilator dependent person. a, b, and c are considerations the patient should entertain in making the decision to consent; and d to be judged by the health care team. If no consent, by proper legal authority.)

--1-- --11.1_

4. Most important factor is reversibility of primary disease process.

--1-- --11.1_

5. Optional ventilation of an elderly person can usually occur after discussion with patient and their family taking into account all of the above factors. If the patient is mentally competent, after information is given, then the decision can be made by the patient. If the patient is incompetent, the family can decide.

--1-- --11.1_

6. None of the above. Rarely a patient will be a candidate for home mechanical ventilation and all (a through d) would have to apply before the decision is made to institute mechanical ventilation. These patients almost always have chronic degenerative neurological diseases such as ALS.

--1-- --11.1_

7. Reason (a) we consider to be the most important reason to place an individual on long term mechanical ventilation. Certainly b-d are looked at and considered in the decision. In addition patient choice is also extremely important in the decision making process.

--1-- --11.1_

8. I feel that the primary reason must be viewed from the patient's eyes. Thus I do not feel comfortable answering this question.

--1-- --11.1_

TABLE 6. (continued)

9. All the above listed reasons show a very cold calculating approach to human life. It seems to be forgotten that most patients from the senior citizens group who need or are on mechanical ventilation are mentally intact and WANT TO LIVE. They have had a productive life in an earlier age, they have paid taxes, they have built the prosperity of this country, raised family, paid for the education of the younger generation and have served their country in many different ways. It will be only fair that their fellow men give them the chance to live as long as they enjoy life even if they are on mechanical ventilation. My patients, 9 of 12, are alert and bright and in the past professionals. Unfortunately they either have no family or their families fear taking them home and caring for them. There are no health related facilities or nursing homes (a cheaper alternative to the problem) which are equipped or staffed to take care of patients on respirators.

The three non COPD patients were post CPR and put on respirators. Even if by physician's discretion the mechanical ventilation is found to be a waste of effort--one cannot take them off the respirator by state law. One way is to wean them if it is possible which is very rare.

The patient has the willingness to accept the ventilator.

--1-- _11.1_

5. Response to question 9: In your opinion, what is the most appropriate definition of "prolonged ventilator dependency"?

Responses to this question varied widely and diverged from the definition used in the data inventory, which was persons 65 and over who have required mechanical assistance for breathing (artificial ventilation) at least 4 hours per day over at least a two week time period. The greatest variance in answers was in the duration of time spent on the ventilator to qualify a patient as being "prolonged ventilator dependent". The definition of the amount of time on a ventilator ranges from two days to 3 months. The definitions provided by the nine institutions that responded to this question are listed below.

- > 48 hours, for a portion or all of the day
- > 7 days
- > 2 weeks
- > 4 hours per day for at least 2 weeks
- > 4 hours per day for at least 4 weeks continuously
- > 30 days
- > 3 months

T48LF 6. (continued)

One institution did not use a time referent in its definition. Three institutions mentioned other issues in addition to the time referent, which are listed below.

The need of informed consent in the institution or continuation of assisted ventilation especially in the case where it may be applied to a person who feels that his/her life is prolonged unjustifiably because it has no quality or significance.

Patients who are dependent on mechanical ventilation to sustain life and to improve the quality of life are characterized by the following criteria:

1. after many attempts by a skilled respiratory care team is not able to be weaned from mechanical ventilation.
2. requires mechanical ventilation continuously or intermittently to prevent respiratory failure.

The age of a patient should never be a factor against rendering medical care including life support. The majority of our patients in the rehabilitation unit are maintained on portable respirator units via trach or mouth piece to increase their mobility and hence their rehabilitation potential and independence

• These questions are taken from the Regional Institutions Case Studies Data Inventory. See Appendix F.

•• Canadian health funds.

PART III*

COMMUNITY CASE STUDIES

Introduction

Chicago and New York City were chosen as the two community sites to study the institutions and resources available for ventilator assisted individuals in those cities. This provides another tier of analysis--at the community level--to complement the perspectives gained from the national data inventory, and regional institutions case studies. It provides an opportunity to look at the network of institutions that may serve VAIs in a given community--both those that are chronic care or rehabilitative in focus and those that are more acute-care oriented. Ann Koterla, M.B.A., at the Chicago chapter of the American Lung Association, collected data in Chicago. Howard Robboy, Ph.D. and Candice Clark, Ph.D. collected data in New York City.

Methodology

The Regional Data Inventory (see Appendix F) was administered to hospitals, nursing homes and rehabilitation institutes in Chicago and New York City. The institution was contacted by telephone and the interviewers conducted the data inventory with an individual knowledgeable about VAIs in their facilities. There were problems in obtaining complete data from all of the institutions. For example, the respondents for 82% of

* This section was principally prepared by Susan N. Dunmire, M.A., Research Project Assistant. The author gratefully acknowledges the information provided by Ann Koterla, M.B.A., Howard Robboy, Ph.D., and Candice Clark, Ph.D.

the patients in Chicago refused or were not able to give specific ages for these patients. Likewise, no exact payment sources were given for the 44 patients identified in Chicago, since the site respondents were not generally knowledgeable about payment sources and time would be required to check patient records. Two of the respondents in Chicago did not provide the length of time on the ventilator and so these ten patients are omitted from the study. There was uncertainty as to whether or not they qualified as prolonged ventilator assisted.

The information from New York City is less detailed than that from Chicago. This may be attributed to the time constraints of the interviewer, as well as to difficulty in identifying the knowledgeable person in the institution, establishing contact with him/her and convincing him/her to participate in the data inventory. Releasing patient information, even though it is not identified by name or number, is considered confidential by many health professionals, and they are sensitive to release such information to someone on the telephone.

COMMUNITY CASE STUDIES
Chicago

Findings

Table 7 lists the 44 patients from the five institutions that reported VAIs 65 and over. These data are summarized in Table 8.

Age and Diagnosis

In Table 8, five hospitals of the 31 reporting institutions listed VAIs 65 and over. The 31 reporting institutions were comprised of 14 nursing homes, two rehabilitation institutes and ten hospitals. Forty-four patients were identified as VAIs, with the age range being from 65 - 80, with a mean age of 70. The most prevalent primary diagnosis was respiratory-related (84.1%). Cardiac complications were the greatest percentage of secondary diagnoses (60%). Respiratory diagnoses were the greatest percentage of diagnoses leading to the individual being ventilator assisted (77.3%).

VLOS, VHRS, EVLOS

The time spent on the ventilator clustered at both ends of the spectrum, with 22.7% of the patients on the ventilator 14 - 30 days, 25.0% of the patients on the ventilator 6 - 12 months, and 20.5% of the patients on the ventilator more than a year. 45.5% of the patients were on the ventilator from 12 - 23 hours, and 54.5% were on the ventilator from 23 - 24 hours. In response to the question of expected additional time on the ventilator, 47.7% of the patients were in a weaning program, and 27.3% of the patients were classified as long-term continuous cases.

Other Issues

Cost. Payment sources were not provided other than that some of the patients were paid in part by Medicare and some by Medicaid. Specific percentages were not given. However, four institutions did report an approximate amount billed per day. The range was \$185 - 500, with the mean at \$352.50 (See Table 9).

VAIs: Increase, decrease or stay the same? In the past month, 15.4 % of the institutions reported that the numbers of VAIs had increased. 38.5% of the institutions reported that the numbers of VAIs had decreased and 46.2% reported that the numbers of VAIs stayed about the same. Looking ahead into the next six months, 64.3% expect to see an increase in the number of VAIs, no respondent expected to see a decrease, and 35.7% expected the numbers would stay about the same. Reasons cited for an increase in VAIs were 1) colder weather is the season for respiratory problems, 2) because of DRGs, private institutions are transferring VAIs to the public institutions, 3) one institution receives referrals from an affiliated nursing home, and 4) as funds diminish, the family tends to leave the patient in the hospital.

Opinion: Why place a patient on mechanical ventilation other than for life-saving purposes? Over twenty-three percent of the institutions responded that one of the main reasons for placing a patient on a ventilator was to enable him/her to continue a productive life. The same percentage of the institutions agreed that one of the main reasons was that the patient has a reasonable level of mental competence. None of the respondents said that one of the main reasons was that the patient has available support persons to care for him/her or that

the patient has appropriate coverage or reimbursement. About one-third agreed that there was no other main purpose than life-saving. Another 30.8% agreed that the main purpose was to facilitate post operative recovery. One of the thirteen (7.7%) mentioned limited family resources.

Appropriate definition of "prolonged ventilator dependency".

The time frame of the definitions suggested ranged from more than 7 days to more than 30 days. One respondent stressed the quality of life in his definition: The ventilator offers the opportunity to sustain and prolong the individual's life with the quality depending on the family and support. Other respondents take a more clinical view, mentioning that it depends on the diagnosis, whether or not ventilation is considered prolonged. Another respondent classified prolonged as a patient who cannot be weaned from the ventilator. These variety of answers suggest that the point of view of the respondent and his or her profession, influence the definition of prolonged mechanical assistance.

COMMUNITY CASE STUDIES
New York City

Findings

Table 11 summarizes the data from the profile of cases reported in Table 10. The total number of VAIs in 9 institutions is 54. Almost half (46.7%) of the diagnoses for those 15 VAIs for which data were available were respiratory, 26.7% were cardiac complications and 20.0% were listed as 'other'. No distinction was made between primary and secondary diagnosis, and the diagnosis leading to the individual being ventilator assisted. The number of days on the ventilator ranged from 21 to 1095 days in the five institutions that reported VLOS. Forty percent (40.0%) of the patients were on the ventilator 6 - 12 months. One third (33.3%) were on the ventilator 21 - 30 days, and 20.0% were on 1 - 3 months. All of the institutions reported their VAIs on the ventilator 24 hours per day. Unfortunately, these data are too incomplete to draw any conclusions or make comparisons with the Chicago study.

Conclusions

An extensive community study could provide a complete picture and a basis for comparison of the VAI population served by a network of acute, chronic care and rehabilitative institutions in a given area. Due to the two month time constraint, an extensive study was impossible. Ms. Koterla spent many hours trying to obtain the information in Chicago. Even then, there were problems of reaching the most knowledgeable person, and then allaying their fears about confidentiality.

If a future study is to be conducted, this portion of the study could be enhanced by conducting it in the same manner as the regional institutions case studies. Send a mail inventory to a key individual and follow up with phone calls until the data are received. This microcosmic study in several selected communities may result in the most accurate and composite view of the systems of care available for ventilator assisted individuals.

TABLE 7.

COMMUNITY CASE STUDIES
CHICAGOData Inventory: Profile of Cases Reported

VAI	AGE	DIAGNOSIS	UNIT	VLDS	VHRS	EVLOS	PAYMENT SOURCES				
				(days)	(hours)	(days)	Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
			Ventilator Care Program	94	24	Long term Continuous Cases					
1	65	a) Diabetes/ hypertension					1	2	3	4	5
		b) Post Cardiac Arrest					(%)	(%)	(%)	(%)	(%)
		c) Post Cardiac Arrest									
2	65	a) Multiple CVA's		874			1	2	3	4	5
		b) Comatose					(%)	(%)	(%)	(%)	(%)
		c) Multiple CVA's									
3	65	a) Respiratory failure		446			1	2	3	4	5
		b) ALS					(%)	(%)	(%)	(%)	(%)
		c) ALS									
4	65	a) Respiratory failure		332			1	2	3	4	5
		b) COPD					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure, CA right lung									
5	65	a) Respiratory failure		10			1	2	3	4	5
		b) CHF					(%)	(%)	(%)	(%)	(%)
		c) CHF									
6	65	a) Multiple CVA brain stem infection		444			1	2	3	4	5 Patient
		b) Comatose and Quadraplegic					(%)	(%)	(%)	(%)	(%)
		c) Multiple CVA									
7	65	a) Chronic respiratory failure		164			1	2	3	4	5
		b) ALS/Diabetes					(%)	(%)	(%)	(%)	(%)
		c) ALS									
8	65	a) Respiratory failure		316			1	2	3	4	5
		b) COPD/Congestive heart failure					(%)	(%)	(%)	(%)	(%)
		c) COPD									

TABLE 7. (continued)

VAI	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
9	65	a) Respiratory failure		299			1	2	3	4	5
		b) COPD/CHF/ASHD					(%)	(%)	(%)	(%)	(%)
		c) COPD/CHF/ASHD									
10	65	a) Respiratory failure		410			1	2	3	4	5
		b) CVA Aphasia					(%)	(%)	(%)	(%)	(%)
		c) CVA									
11	65	a) Respiratory failure		395			1	2	3	4	5
		b) Aspiration pneumonia					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
12	65	a) Respiratory failure		370			1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
13	65	a) Respiratory failure		29	16	Weaning program		2	3	4	5
		b) ALS					(%)	(%)	(%)	(%)	(%)
		c) ALS									
14	65	a) Chronic respiratory insufficiency		417			1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c) Chronic respiratory insufficiency									
15	65	a) Respiratory failure		162			1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
16	65	a) Respiratory failure		10			1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
17	65	a) Respiratory insufficiency		123			1	2	3	4	5
		b) Post cardiac arrest/diabetes					(%)	(%)	(%)	(%)	(%)
		c) Respiratory insufficiency									

TAP 7. (continued)

VAT	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
18	65	a) Respiratory failure	*	136	*	*	1	2	3	4	5
		b) Paraplegia					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
19	65	a) Respiratory failure	*	977	*	*	1	2	3	4	5
		b) CHF, Muscular Sclerosis, Quadraplegia					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
20	65	a) Respiratory failure	*	9	*	*	1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
21	65	a) Respiratory failure	*	91	*	*	1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
22	65	a) Respiratory failure	*	153	*	*	1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
23	65	a) Respiratory failure	*	263	*	*	1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
24	65	a) Respiratory failure	*	7	*	*	1	2	3	4	5
		b) Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									
25	65	a) Respiratory insufficiency	*	55	*	*	1	2	3	4	5
		b) Seizures insufficiency					(%)	(%)	(%)	(%)	(%)
		c) Respiratory insufficiency									
26	65	a) Respiratory failure	*	46	*	*	1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure									

TABLE 7. (continued)

VAT	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
27	65	a)Respiratory failure	"	125	"	"	1	2	3	4	5
		b)Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
28	65	a)Respiratory failure	"	4	"	"	1	2	3	4	5
		b)Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
29	65	a)Respiratory failure	"	"	"	"	1	2	3	4	5
		b)Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
30	65	a)Respiratory failure	"	"	"	"	1	2	3	4	5
		b)Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
31	65	a)Respiratory failure	"	"	"	"	1	2	3	4	5
		b)Post cardiac arrest					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
32	66	a)Myasthenia Gravis	ICU	30	18	Go home on it	1	2	3	4	5
		b)Respiratory failure					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
Surgical											
33	68	a)Coronary artery disease	ICU	17	24	Still on vent	1	2	3	4	5
		b)Coronary bypass					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
Medical											
34	68	a)Respiratory failure	ICU	19	24	Weaned off	1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c)Respiratory failure									
35	75	a)ARDS	MICU	18	24	Expired	1	2	3	4	5
		b)					(%)	(%)	(%)	(%)	(%)
		c)ARDS									

TABLE 7. (continued)

VAI	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
36	65	a) Lung Cancer	SICU	14	24	OFF	1	2	3	4	5
		b) _____					(%)	(%)	(%)	(%)	(%)
		c) Thoracotomy					(%)	(%)	(%)	(%)	(%)
37	72	a) COPD	MICU	150	24	UNKNOWN	1	2	3	4	5
		b) _____					(%)	(%)	(%)	(%)	(%)
		c) COPD					(%)	(%)	(%)	(%)	(%)
38	67	a) Lung Cancer	ICU	30	24	UNKNOWN	1	2	3	4	5
		b) _____					(%)	(%)	(%)	(%)	(%)
		c) Respiratory failure					(%)	(%)	(%)	(%)	(%)
39	80	a) Pneumonia	ICU	53	24	UNKNOWN	1	2	3	4	5
		w/pleural effusion									
		c) Respiratory failure					Primary (%)		Secondary (%)		(%)
40	NA*	a) COPD	ICU	30	24	LIFETIME	1	2	3	4	5
		b) CHS					(%) X	(%)	(%) X	(%)	(%)
		c) COPD					(%)	(%)	(%)	(%)	(%)
41	NA*	a) COPD	ICU	30	24	MAY BE WEAN	1	2	3	4	5
		b) CHS					(%) X	(%)	(%)	(%)	(%)
		c) Pneumonia					(%)	(%)	(%)	(%)	(%)
42	NA*	a) COPD	ICU	30	24	" " "	1	2	3	4	5
		b) CHS					(%) X	(%)	(%)	(%)	(%)
		c) COPD					(%)	(%)	(%)	(%)	(%)
43	NA*	a) COPD	ICU	35	24	14	1	2	3	4	5
		b) CHS					(%) X	(%)	(%)	(%)	(%)
		c) Brain Tumor					(%)	(%)	(%)	(%)	(%)
44	NA*	a) COPD	ICU	180	24	14	1	2	3	4	5
		b) _____					(%)	(%)	(%)	(%)	(%)
		c) COPD					(%)	(%)	(%)	(%)	(%)

* NA: NOT AVAILABLE

TABLE 8.

COMMUNITY CASE STUDIES
CHICAGO
Summary Response Rate Profile

Reporting Institutions

Total number: 31

Nursing homes: 14

Rehabilitation Institutes: 2

Hospitals: 10

Total number with VAIs 65 and older: 5 Hospitals

VAIs Reported

Total number age 65 and older: 44

Age range: 65-80*

Mean age: 70

- * This number is based on 8 patients. Only one institution would report exact ages.

Diagnoses

	Total	Percent (%)
Primary		
Cardiac complications	1	2.3 %
(ie. CHF, Aortic aneurysm)		
Neurological/neuromuscular	3	6.8
(ie. ALS, CVA, Polio)		
Respiratory	37	84.1
(ie. COPD, ARDS, pneumonia)		
Other	3	6.8
(ie. trauma, G.I. system, cancer)		
Total	44	100.0
Secondary		
Cardiac complications	21	60.0
(ie. CHF, Aortic aneurysm)		
Neurological/neuromuscular	7	20.0
(ie. ALS, CVA, Polio)		
Respiratory	5	14.3
(ie. COPD, ARDS, pneumonia)		
Other	2	5.7
(ie. trauma, G.I. system, cancer)		
Total	35	100.0
Leading to being ventilator assisted		
Cardiac complications	2	4.5
(ie. CHF, Aortic aneurysm)		
Neurological/neuromuscular	6	13.6
(ie. ALS, CVA, Polio)		
Respiratory	34	77.3
(ie. COPD, ARDS, pneumonia)		
Other	2	4.5
(ie. trauma, G.I. system, cancer)		
Total	44	99.9

TABLE 8. (continued)

Reported Time on a Ventilator

Total Time (VLOS) Range: 4*-977 days			Hours per Day (VHRS) Range: 12 - 24 hours		
	Total Number	Percent (%)		Total Number	Percent (%)
4 - 13 days	_8_	_18.2 %	<12 hours	_0_	_0.0 %
14 - 30 days	_10_	_22.7	12 - 23 hours	_20_	_45.5
1 - 3 months	_4_	_9.1	23 - 24 hours	_24_	_54.5
3 - 6 months	_2_	_4.5	Total patients	_44_	100.0
6 - 12 months	_11_	_25.0			
> 12 months	_9_	_20.5			
Total patients	_44_	100.0			

* Please note: Data from eight patients are included who were on the ventilator less than our defined time of 14 days.

Expected Additional Time on the Ventilator (EVLOS)

Range: Weaned off - Lifetime

	Total Number	Percent (%)
Lifetime	___1___	__2.3_ %
Long term continuous	__12__	_27.3_
Weaning program	__21__	_47.7_
14 days	__2_	__4.5_
Unknown	__5_	_11.4_
Weaned off	__2_	__4.5_
Expired	__1_	__2.3_
Total patients	__44__	100.0_

Data on payment sources were not provided by the institutions.

TABLE 9.

COMMUNITY CASE STUDIES
CHICAGO
Other Issues Regarding Prolonged Mechanical
Ventilation for VAIs*

1. Response to question 5: What is the approximate amount billed per day for the elderly VAIs in your system?

Range of cost (\$) 185 - 500

Mean cost (\$) __352.50__

Total number of institutions responding __4*_

- * Nine additional institutions responded 'Don't know'.

2. Response to question 6: In the past month have the numbers of VAIs in your system 65 and over, increased?... decreased?... or stayed about the same?

	Total Number	Percent (%)
Increased	__2__	_15.4_ %
Decreased	__5__	_38.5_
Stayed about the same	__6__	_46.2_
Total	__13__	100.1_

3. Response to question 7: Do you think that in the next six months the number of VAIs in your system 65 and over, will increase?... decrease?... or stay about the same?

	Total Number	Percent (%)
Increase	__9__	_64.3_ %
Decrease	__0__	_0.0_
Stay about the same	__5__	_35.7_
Total	__14__	100.0_

TABLE 9. (continued)

Explanations:

Increase

1. Due to DRGs private institutions are pushing them onto public institutions.

__1__ _7.1_

2. Colder weather. The season for respiratory problems.

__6__ 42.9_

3. Affiliated with nursing homes that refer patients.

__1__ _7.1_

4. Run out of funds and family leaves patient in the hospital.

__1__ _7.1_

Stay about the same

1. Perhaps slight increase due to improved technology.

__1__ _7.1_

4. Response to question 8: In your opinion, what are the main reasons for placing an elderly person on a ventilator other than for life-saving purposes? (The respondent was asked to circle ALL THAT APPLY. Therefore, one institution may have chosen several or all of the given answers, and the percentages may not total 100%.)

Total institutions responding: 13

	Total Number of Responses	Percent (%)
a. enable patient to continue a productive life	__3__	__23.1_
b. patient has available support persons to care for him/her	__0__	___0.0_
c. patient has appropriate coverage or reimbursement	__0__	___0.0_
d. patient has a reasonable level of mental competence	__3__	__23.1_

TABLE 9.

e. other (explanations listed)

1. None other than life-saving.

__4__	__30.8_
-------	---------

2. Post operative.

__4__	__30.8_
-------	---------

3. Limited family resources. No home to discharge to. Unanswered questions by other hospitals contacted about home care. Vast support base is necessary to place back in the home.

__1__	__7.7_
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5. Response to question 9: In your opinion, what is the most appropriate definition of "prolonged ventilator dependency"?

Responses to this question varied widely and diverged from the definition used in the data inventory, which was persons 65 and over who have required mechanical assistance for breathing (artificial ventilation) at least 4 hours per day over at least a two week time period. The greatest variance in answers was in the duration of time spent on the ventilator to qualify a patient as being "prolonged ventilator dependent". The definition of the amount of time on a ventilator ranges from more than 7 days to more than 30 days. The definitions provided by the 12 institutions that responded to this question are listed below.

- > 7 days
- > 2 weeks
- at least 2 weeks to 2 months 24 hours/day
- > 3 weeks and unable to be weaned.
- > 30 days

In addition to the time referent given, the following definitions were suggested.

Depends on the diagnosis. Sometimes anything beyond a couple of days is prolonged.

Ventilator offers the opportunity to sustain and prolong the individual's life with the quality depending on the family and support.

One that we cannot wean from the ventilator.

TABLE 9. (continued)

Person in need of no form of intensive care other than ventilator. People who do not need hospitalization. someone who will never be able to breathe on own--not just to get them over a rough spot.

Intermediate or temporary life support/maintenance until physician can intervene.

-
- * These questions are taken from the Regional Institutions Case Studies Data Inventory. See Appendix F.

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Table 10.

COMMUNITY CASE STUDIES
NEW YORK
Data Inventory: Summary Profile of Cases Reported

<u>Institution</u>	<u>#VAIs</u> >65	<u>Age</u>	<u>Diagnosis</u>	<u>Unit</u>	<u>VLOS</u>	<u>VHRS</u>	<u>EVLOS</u>	<u>Payment</u>
1	5	NA*	Neurological CVA Trauma	NA*	1-3 years	24	NA*	NA*
2	7	NA*	Post CVA Post cardiac	NA*	300 360 240 240 240 180	24	NA*	NA*
3	1	NA*	NA*	NA*	NA*	NA*	NA*	NA*
4	0	---	---	---	---	---	---	---
5	5	NA*	COPD; CHF Cancer COPD; congestive heart failure COPD; CHF COPD; CHF	NA*	90 60 60 30 30	24 24 24 24 24	NA*	NA*
6	3	NA*	NA*	NA*	NA*	NA*	NA*	NA*
7	10	NA*	COPD CHF	ICU & CCU	NA*	24	NA*	NA*
8	20	NA*	NA*	NA*	NA*	NA*	NA*	Medicare & Medicaid
9	1	NA*	COPD	NA*	30	24	NA*	NA*
10	2	NA*	CA of Thymus Aortic Aneurysm	NA*	>21 >21	NA*	NA*	Private Insurance Medicare & Private Insurance

* NA: Not Available

TABLE 11.

COMMUNITY CASE STUDIES
NEW YORK CITY
Summary Response Rate Profile

Reporting institutions

Total number: 10

Total number with VAIs 65 and older: 9

VAIs Reported

Total number age 65 and older: 54

Age range: NA*

Mean age: NA*

Diagnoses

	Total	Percent (%)
Cardiac complications (ie. CHF, Aortic aneurysm)	4	26.7 %
Neurological/neuromuscular (ie. ALS, CVA, Polio)	1	6.6
Respiratory (ie. COPD, ARDS, pneumonia)	7	46.7
Other (ie. trauma, G.I. system, cancer)	3	20.0
Total	15	100.0

Reported Time on a Ventilator

Total Time (VLOS)

Range: 21 - 1095 days

	Total Number	Percent (%)
21 - 30 days	_5_	_33.3 %
1 - 3 months	_3_	_20.0
3 - 6 months	_0_	_0.0
6 - 12 months	_6_	_40.0
>12 months	_1_	_6.7
Total patients	_15_	100.0

PART IV.*

CONCLUSIONS AND RECOMMENDATIONS

A paucity of data exists on the number and characteristics of the elderly on prolonged mechanical ventilation and the financial, service-related, and ethical issues surrounding their care. The research reported here represents an effort, with limited time and resources, to gather data at a variety of levels--nationally, regionally, and community-wide--on this population in an effort to inform some of these issues.

This research was conducted principally by the staff of the Center for Health Administration Studies (CHAS), The University of Chicago, during the months of July and August, 1985, with input and assistance from colleagues at the American Association of Respiratory Therapists, the Chicago Lung Association, Trenton State College, Montclair State College, Rutgers University and Children's Memorial Hospital (Chicago).

There are methodological limitations with each of the data sets reported here, which are clearly stated in the discussion of the study methodology in the respective sections of the report. These limitations must be borne in mind in analyzing and interpreting the findings and in considering how generalizable they are to the universes the various data collection efforts were intended to represent.

* This section was principally prepared by Lu Ann Aday, Ph.D., Research Associate (Associate Professor), Associate Director for Research.

The findings, in general, suggest that the number of ventilator assisted elderly is quite small. There is apt to be substantial under-reporting in the American Association of Respiratory Therapists (AART) survey summarized here. That study estimates approximately 1,236 elderly VAIs in the 37 states for which 1985 data were available, however. The AART state representatives reporting estimated that approximately 1,016 (82%) of these individuals were hospitalized and the balance (220 or 18%) were at home. This represented a rate of 5.3 VAIs per 100,000 elderly in the states reporting. Some of the major regional institutions approached in the regional cases studies had no or very few elderly VAIs. Of the 31 nursing homes, rehabilitation facilities and hospitals contacted in one of the community case study sites, only five hospitals reported having elderly VAIs who met the study criteria--required mechanical assistance for breathing at least 4 hours per day over at least a two week time period.

These elderly individuals on ventilators tended to be the "old" elderly. The mean age of elderly VAIs identified in the regional institutions case studies was 72 and in the community case study for which data were available, the mean age of VAIs for those institutions reporting was 70.

Respiratory-related illnesses (COPD, ARDS, pneumonia) were the conditions reported most often as leading to the individual's actually being on a ventilator. Neurological/neuromuscular and cardiac complications were also frequently mentioned as primary and/or secondary conditions experienced by the VAIs for which

data were reported.

A large proportion of VAIs in both the regional and community case studies were reported to have been on the ventilator less than a year. Over half in the regional and the one community case study reporting these data were on the ventilator practically all day (23-24 hours). Many were expected to remain on a ventilator for the rest of their lives or for an extended period of time.

There was no consensus among those reporting of what criteria accurately defined "prolonged" mechanical ventilation. Estimates ranged from two days (48 hours) to three months or longer. Important criteria cited by many in determining who and how long to ventilate included whether (1) it would enable the patient to continue a productive life; (2) the patient had a reasonable level of mental competence; (3) there was a support system to care for him/her; and (4) appropriate coverage or reimbursement was available.

The AART survey pointed out that over one-third (34.3%) of elderly VAIs (or approximately 349 persons) would be able to go home from the hospital if adequate reimbursement were available. That study estimated an average daily inpatient cost per day of \$824 for VAIs (of all ages), resulting in an annual cost of hospitalization of \$300,760. They compared this to an average estimated monthly home care cost of \$1,853, resulting in an average annual cost of \$22,236. AART then estimated a savings of around \$278,000 from transferring an eligible VAI from the hospital to a home care setting.

The average daily inpatient costs for elderly VAIs for institutions reporting in the regional cases studies was approximately \$938 (slightly higher than the AART estimate of \$824 for all VAIs). The vast majority of hospitalized elderly VAIs identified by these institutions were covered by Medicare and Medicaid.

Financial issues were mentioned as important correlates of probable trends in the numbers of elderly VAIs in institutions like the ones studied. With the advent of prospective payment, some respondents argued that community, acute-care hospitals will no longer be able to "afford" to care for long-term elderly VAIs. Representatives of chronic care and rehabilitation facilities then tend to expect an increase in the number of elderly VAIs in their institutions, as a result of increased referrals from these community hospitals.

In sum, these preliminary data suggest that though the number of elderly VAIs on prolonged mechanical ventilation is quite small overall, to the extent they remain on ventilators in inpatient settings, the costs of caring for them may be high. There is evidence, however, that many of these individuals are not necessarily terminally ill. Considerations of the potential of the individual--physically and mentally--to carry on a productive life are weighted heavily in caregivers' decisions to ventilate, as is the availability of familial or other support systems to care for them. One source suggests that about one in three elderly VAIs in inpatient settings could go home, if funding were available and that the resultant savings to the public programs that principally fund these individuals (Medicare

and Medicaid) could be substantial.

Much more research needs to be done on this population to most fully and accurately address these issues, however. As indicated through an inventory of national organizations dealing with health care issues of the elderly, some have data that might be used to glean more insights about the prevalence, utilization, and cost of caring for this population. The methodologies developed here could be applied in a more systematic and comprehensive nationwide data gathering effort, if funds and time were available. These issues will not "go away" as the population continues to age and the technologies for sustaining life continue to increase in number. The research reported here represents an effort to begin to shed light on these issues for one particular group of the elderly--those on prolonged mechanical ventilation.

PART V

EPILOGUE

A preliminary report on Task 3 was submitted to the Office of Technology Assessment in September 1985. Subsequent to transmitting that report, responses from two more regional case study sites, contacted originally, were returned to the Center for Health Administration Studies. The data from these institutions are incorporated in the revised tables and text in Part II of this final report.

In addition, OTA raised several clarifying questions in response to the original (September) report. These questions and our responses to them are summarized below.

Older patients have higher hospital costs than persons under 65. Why?

Is this comment in response to the first sentence on page 69 of the September report [now page 73]: "The average daily inpatient costs for elderly VAIs for institutions reporting in the regional case studies was approximately \$944 [revised estimate= \$938] (slightly higher than the AART estimate of \$824 for all VAIs)." The cost comparison in this statement is between the mean cost for VAIs age 65 and over reported in the regional case studies and the AART cost estimate for all ages of VAIs. The variation in these two cost figures could be due to the total number of institutions reporting cost data, as well as variations in the age of the ventilator patients. Whatever the explanation for this variation, the intent of the statement was not to prove or to explain that older patients have higher costs than persons under 65. This statement cannot be supported with data from this study.

Explain your conclusion that "many" patients receiving mechanical ventilation are "not necessarily terminally ill" (p. 69) [now page 73]. What are some likely medical conditions leading to this?

COPD, polio, ARDS, respiratory failure

How widespread is this practice?

Cannot determine from this study.

Are these the same individuals who are considered able to go home?

This is suggested, although it cannot be clearly proven by the data. The AART study offered the number of patients deemed able to go home, if funding were available, but gave no diagnoses. The regional case studies provided the diagnoses, but not clarification of which patients or how many patients could be deemed able to go home.

Please clarify your definition of "terminally ill".

The definition used is that from Deciding to Forego Life-Sustaining Treatment, the President's Commission for the Study of Ethical Problems in Medical and Biomedical and Behavioral Research, March 1983, p. 25-26. This is not an 'ironclad definition', but one which varies according to the individual's condition, taking into consideration the patient's mental capacity, will to live, existence of a supportive family and continuance of a productive life with mechanical assistance. The essence of the meaning is that mechanical assistance is being used to "enhance life", not just to "prolong death."

Does all the data you obtained from the Veterans Administration relate to the Chicago VA? We would like some information from the VA central office as well.

In the report, all the data was from the Veterans Administration in Chicago. Since the report was submitted, information on the VA data system has been obtained from the Veterans Administration in Washington, D.C. The data are filed and coded by diagnoses. The patient records for patients age 65 and over who may potentially be VAIs could be reviewed to identify how many VAIs exist. Another option for collecting data would be to survey all the VA hospitals using the regional data inventory. Both options would require a great number of manpower hours. The procedure to obtain this information is to contact Mr. Walters, Administrator of VA affairs, 810 Vermont Ave., N.W., Washington, D.C. 20420, (202) 389-3781.

Wherever possible, break data on the elderly into more specific age groups.

In Part II, The Regional Case Studies, there was a total of 46 patients (in the final report). Broken down by age, 21 were between 65 and 70, 19 were between 71 and 80, and 6 were 81 or older. With regards to the primary diagnoses, 82.0% of the patients 65-70 were diagnosed as neurological/neuromuscular or respiratory. In the 71-80 age range, 87.5% were diagnosed as neurological/neuromuscular or respiratory and 100% of the patients age 81 and over had these same diagnoses. Regarding the secondary diagnoses, 57.1% of patients 65-70 had diagnoses of 'other' and 28.6% had respiratory diagnoses. For patients age 71-80, 57.1% had respiratory diagnoses and 28.6% had cardiac diagnoses, while 75.0% of the patients 81 and older had cardiac diagnoses. The diagnoses most commonly leading to being ventilator assisted for patients age 65-70 were neurological/neuromuscular at 55.6% and were evenly spread over the other diagnoses. For patients 71-80, 40.0% had cardiac diagnoses and 40.0% had neurological/neuromuscular diagnoses. The diagnoses for patients 81 and over were evenly distributed between 'other' and neurological/neuromuscular at 50.0% each.

The length of time on the ventilator (VLOS) ranges from 13-8200 days for patients age 67-70, from 13-2277 days for patients age 71-80 and from 27-1825 days for patients 81 and older. For patients 65-70, 31.3% were on the ventilator for one to three months and 37.5% for 12 months or more. Of patients 71-80, 37.5% were on the ventilator for one to three months, 18.8% for three to six months, and 18.8% for more than 12 months. Fifty percent of patients 81 and older were on the ventilator for one to three months. The majority of patients in each age category were on the ventilator 23-24 hours, with 78.9% of the patients 65-70, 68.4% of the patients 71-80 and 100% of the patients 81 and older. The majority responses for the expected length of stay on the ventilator (EVLOS) were 'until death' and 'lifetime', totaling 84.2% for patients 65-70, 66.7% for patients 71-80 and 83.3% for patients 81 and older. Since the overwhelming majority of patients have Medicare and Medicaid listed as their payment source, breakdowns by age are not that informative.

Can you say more about costs borne by private agencies and foundations?

The data collected do not reveal anything about these costs.

Is there evidence of rationing? unmet need? or unjustified use?

In the data collected, there is no evidence of rationing or unjustified use. With regards to unmet need, there is evidence in Table 6, page 42 of September report (now page 44), of a waiting list for ventilators, and the need for funding and appropriate chronic care facilities to adequately meet the needs of this population.

On page 24, you refer to proprietary information that will be released to OTA when permission is received from Travenol. What is the status of this? Were data also requested from the other companies you contacted, i.e. Foster Medical, American Abbey Home Care and Quality Care? (If not, OTA can contact them directly).

A follow-up call was made to Jim Retel at Travenol. He said that if the information would be used in the public domain, they would not want it released, because their competition would have access to it. However, if the information would be used strictly internally by Congress, then they would release it. Information was requested from Foster Medical, American Abbey Home Care and Quality Care by telephone, however no formal request was made due to the time limitation because it would take several weeks to receive approval from the administration to obtain the data and then to actually receive it. Quality Care did not have accessible data and would have to conduct a survey in order to provide data.

APPENDIX A.

NATIONAL DATA INVENTORY
AART SURVEY OF VENTILATOR ASSISTED INDIVIDUALS
AART QuestionnaireCOST COMPARISON FOR VENTILATOR SUPPORTHOSPITAL vs. HOME ENVIRONMENT

1. What is the number of ventilator dependent patients in your state? _____
2. Of these, how many are cared for in the:
A. hospital setting _____
B. home setting _____
C. other _____
3. What is the age breakdown of the numbers indicated in question 1?
A. 17 or younger _____
B. 18 - 64 _____
C. 65 - older _____
4. Please list, by age group, how many ventilator dependent patients are
cared for in the hospital setting:
A. 17 or younger _____
B. 18 - 64 _____
C. 65 - older _____
5. If reimbursement were available for home rendered ventilator support,
how many, by age group, would be able to take advantage of this?
A. 17 or younger _____
B. 18 - 64 _____
C. 65 - older _____
6. What is the average daily total charge (respiratory plus non-respiratory
related) to an in-the-hospital patient on a ventilator?
\$ _____
7. What is the average monthly total charge (respiratory plus non-respiratory
related) to an in-the-home patient on a ventilator?
\$ _____

Contract 533-4935.0

000340

(THE FOLLOWING LISTING WAS REQUESTED ON 1985 SURVEY ONLY)

Please complete for each facility surveyed:

<u>Hospital Name</u>	<u>Bed Size</u>	<u>Town</u>
----------------------	-----------------	-------------

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

In reference to Questions 6 & 7, what components are included in the charges?
(i.e. ventilator, respiratory therapist visits, oxygen, etc.)

Thank for your assistance on this important matter.

State _____ Completed by _____ Telephone _____

APPENDIX B.

NATIONAL DATA INVENTORY
AART SURVEY OF VENTILATOR ASSISTED INDIVIDUALS
List of States Reported

1983

ARKANSAS
COLORADO
CONNECTICUT
FLORIDA
GEORGIA
ILLINOIS
INDIANA
IOWA
KANSAS
KENTUCKY
MAINE
MINNESOTA
MISSOURI
MONTANA
NEBRASKA
NEW JERSEY
NEW MEXICO
OKLAHOMA
TEXAS
VIRGINIA
PENNSYLVANIA*

*DATA NOT INCLUDED IN SOME ESTIMATES.

1985

ALABAMA
ARIZONA
ARKANSAS
CALIFORNIA
CONNECTICUT
FLORIDA
INDIANA
IOWA
KANSAS
KENTUCKY
MASSACHUSETTS
MARYLAND/D.C.
MICHIGAN
MINNESOTA
MISSISSIPPI
MISSOURI
MONTANA
NEBRASKA
NEW HAMPSHIRE
NEW JERSEY
NEW YORK
NORTH CAROLINA
NORTH DAKOTA
OHIO
OKLAHOMA
OREGON
PENNSYLVANIA
RHODE ISLAND
SOUTH CAROLINA
SOUTH DAKOTA
TENNESSEE
TEXAS
VERMONT
VIRGINIA
WASHINGTON
WEST VIRGINIA
WISCONSIN

APPENDIX C.

NATIONAL DATA INVENTORY
NATIONAL ORGANIZATIONS
Key Informant Organizations

Acute (Critical) Care Associations (Respiratory Care Orientation)

- (CHAS) American Academy of Family Physicians
1740 West 92nd St.
Kansas City, MO 64114
(800) 821-2512
- (CHAS) American Association of Respiratory Therapy (AART)
1720 Regal Row
Dallas, TX
(214) 630-3540
- (CHAS) American College of Chest Physicians (ACCP)
911 Busse Highway
Park Ridge, IL 60068-2375
(312) 698-2200
- (AK) American Lung Association
- (AK) American Medical Association
Department Allied Health & Education
535 N. Dearborn
Chicago, IL 60610
(312) 645-4697
- (CHAS) American Nurses' Association, Inc.
2420 Pershing Rd.
Kansas City, MO 64108
(816) 474-5720
- (CHAS) American Occupational Therapy Association
1383 Piccard Dr.
Suite 300
Rockville, MD 20850
(301) 948-9626
- (AK) American Osteopathic Association
212 E. Ohio St.
Chicago, IL 60611
(312) 280-5800
- (AK) American Physical Therapy Association
1111 North Fairfax
Alexandria, VA 22314
- (CHAS) American Thoracic Society (ATS)

APPENDIX C. (continued)

- (CHAS) Critical Care Society
Society of Critical Care Medicine
223 E. Imperial Highway, Suite 140
Fullerton, CA 92635
(714) 870-5243
- (AK) National Association of Medical Directors of Respiratory
Care (NAMDRC)
P.O. Box 10832
Chicago, IL 60616
(312) 871-7500
- (CHAS) National Institutes of Health
National Institute on Aging
9000 Rockville Pike
Bethesda, MD 20014
(301) 496-9265
- (AK) Visiting Nurses Association
310 S. Michigan
Chicago, IL 60604

Pertinent Disease-Oriented Associations

- (HR, ALS Association, Inc.
CC) 185 Madison Avenue, Suite 1001
New York, NY 10016
(212) 679-4016
- (CHAS) American Cancer Society
District of Columbia Division
1825 Connecticut Ave. N.W.
Washington, D.C. 10009
(202) 483-2600
- (HR, American Lung Association
CC) 1740 Broadway
New York, NY 10019
(212) 245-8000
- (CHAS) National Foundation for Long Term Health Care
Dr. Paul Kerschner (Executive Director)
1200 15th St., N.W.
Washington, D.C. 20005
(202) 833-2050
- (HR, Polio Information Center
CC) Harriet Bell (Founder)**
510 Main St., Apt. A446
Roosevelt Island, NY 10044

APPENDIX C. (continued)

(AK) Respicare
3521 E. 106th St
Chicago, IL

Organizations dealing with the Elderly

(CHAS) Administration on Aging
General Information
330 Independence Ave., S. W.
Washington, D.C. 20201
(202) 472-7257

(CHAS) American Aging Association
University of Nebraska Medical Center
Omaha, NE 68105
(402) 559-4416

(CHAS) American Association for International Aging
1511 K St., N.W., Suite 1028
Washington, D.C. 20005
(202) 638-6815

(CHAS) American Association of Homes for the Aging
1050 17th St., N.W.
Suite 770
Washington, D.C. 20036
(202) 296-5960

(HR, American Federation for Aging Research (AFAR),
CC) 335 Madison Ave.
New York, NY 10017
(212) 503-7600

(HR, American Geriatrics Society
CC) 220 Central Park South, 11A
New York, NY 10019
(212) 582-1333

(CHAS) American Longevity Association
1000 W. Carson St.
Torrance, CA 90509
(213) 533-2220

(CHAS) Federal Council on Aging
200 Independence Ave., S.W.
Washington, D.C. 20201
(202) 245-2451

(AK) Lifecare
5505 Central Ave.
Boulder, Colorado 80301

APPENDIX C. (continued)

- (CHAS) National Council on the Aging
600 Maryland Ave., S.W.
West Wing 100
Washington, D.C. 20024
(202) 479-1200
- (AK) Rehabilitation Engineering Program
Northwestern University School of Medicine
345 E. Superior
Chicago, IL 60611
(312) 649-8560
- (CHAS) National Geriatrics Society
212 W. Wisconsin Ave.
Milwaukee, WI 53203
(414) 272-4130

Organizations dealing with health care institutions

- (CHAS) American College of Health Care Administrators
4650 East West Highway
P.O. Box 5890
Bethesda, MD 20814
(301) 652-8384
- (AK) American Hospital Association
840 N. Lake Shore Dr.
Chicago, IL 60611
(312) 280-6000
- (CHAS) Commission on Professional Hospital Activities (CPHA)
- (AK) Illinois Association of Rehabilitation Facilities
206 S. 6th St.
Springfield, IL 62701
(217) 753-1190
- (AK) Joint Commission on Accreditation of Hospitals
875 N. Michigan Ave.
Chicago, IL 60611
(312) 642-6061
- (CHAS) National Center for Health Services Research
Room 8-50 B #4
Federal Center Building #2
3700 East-West Highway
Hyattsville, MD 20782

APPENDIX C. (continued)

(CHAS) National Center for Health Statistics
Federal Center Building #2
3700 East-West Highway
Hyattsville, MD 20782
(301) 436-7035

(AK) Veterans Administration
North Chicago VA Hospital
(312) 688-1900

(CHAS) Veterans Administration
810 Vermont Ave., N.W.
Washington, D.C. 20420
(202) 389-3781

Home Care Associations

(AK) American Association for Continuity of Care
Northwestern Memorial Hospital, Chicago
(312) 908-3335

(CHAS) American Federation of Home Health Agencies
Suite S-605, 429 N. St., S.W.
Washington, D.C. 20024
(202) 554-0526

(AK) Assembly of Ambulatory and Home Care Services (AAHCS)
American Hospital Association
840 N. Lake Shore Drive
Chicago, IL 60611

(AK) Illinois Continuity of Care Organization

(CHAS) National Association for Home Care
519 "C" St., N.E.
Washington, D.C. 20002
(202) 547-7424

(CHAS) National Foundation for Hospice and Home Care
519 C St., N.E.
Stanton Park
Washington, D.C. 20002
(202) 547-7424

Associations dealing with alternative site/alternative delivery
systems

(AK) Association for Health Care Coalitions
Hospital Insurance Association of America, Chicago
(312) 322-0830

APPENDIX C. (continued)

Related Trade Association

- (CHAS)-for DME vendors - Glassrock Home Care
(404) 261-0309 or 433-1800 x242
- (AK) - Travenol
Travacare Respiratory Home Service
888 Cambridge Dr.
Elk Grove Village, IL 60007
(312) 952-8836
- (AK) - Foster Medical
5350 Mc Dermott Drive
Berkeley, IL 60163
(312) 344-4777

Home Health Care Providers

- (AK) Aamed
1215 S. Harlem
Park Forest, IL 60130
- (AK) American Abbey Home Care
Chicago, IL
- (AK) HomeCare Associates, Ltd.
(312) 941-7795
- (AK) Upjohn
2605 E. Kilgore Rd.
Kalamazoo, MI 49002
(616) 342-7087
- (AK) Quality Care
100 N. Center Avenue
Rockville Center, N.Y. 11570
(516) 678-3200

Financial Organizations

- (AK) Blue Cross Association
233 N. Michigan
Chicago, IL 60601-5655
(312) 938-7500
- (AK) Department of Health and Human Services
HCFA
Chicago Regional Office
175 W. Jackson Blvd.
Chicago, IL 60604

APPENDIX C. (continued)

- (CHAS) Health Care Financing Administration
200 Independence Ave., S.W.
Washington, D.C. 20201
(202) 245-6726
- (CHAS) Health Insurance Association of America
(312) 332-0800
- (AK) Health Insurance Council of America
(312) 332-0800
- (AK) Health Insurance Council of America
- (AK) Illinois Department of Public Aid
931 E. Washington St.
Springfield, IL 62763
- (AK) Illinois Department of Rehabilitation Services
Springfield, IL 62763
- (AK) Medicare-Medicaid (Federal)
Department Health & Human Services
Health Care Finance Administration
175 W. Jackson Blvd.
Chicago, IL 60604
(312) 353-3822

Please Note:

Abbreviations prior to institution name refer to persons
responsible for contacts:

AK: Ann Koterla
CHAS: The Center for Health Administration Studies
HR, CC: Howard Robboy, Ph.D., Candice Clark, Ph.D.

APPENDIX D.

OFFICE OF TECHNOLOGY ASSESSMENT
VENTILATOR ASSISTED INDIVIDUAL
SURVEY

NATIONAL DATA INVENTORY

The Center for Health Administration Studies at The University of Chicago is conducting a survey of persons 65 and over on prolonged mechanical ventilation for a report by the Office of Technology Assessment (OTA) to Congress. The subjects of this study are persons 65 and over who have required mechanical assistance for breathing (artificial ventilation) at least 4 hours per day over at least a two week time period.

ORGANIZATION _____

INTERVIEWEE _____

ADDRESS _____

TELEPHONE (____) _____

1. Does your organization have information on these individuals?

Yes _____ (GO TO QUESTION 2.)

No _____ (SKIP TO QUESTION 9.)

2. What kind of information do you have? (RECORD VERBATIM.)

2. (continued)

PROBE: Does your data contain...? (CIRCLE APPROPRIATE CODE IF ALREADY ANSWERED. REFER TO QUESTION 7 FOR MORE DETAIL.)

	Yes	No
a) Does your data contain any diagnosis information?	1	2
b) Does your data contain any information on the number of days and hours per day the individual has been or might be on a ventilator?	1	2
c) Does your data contain any information about the source of payment for services?	1	2
d) Does your data contain any information about the cost or amount billed for these individuals?	1	2

3. What would be required to obtain these data on VAIs from your files?

4. How long would it take to obtain this information?

5. How many Ventilator Assisted Individuals (VAIs) have you identified?

6. How many of these VAIs are 65 and older?

7. ASK OR CALL BACK FOR FOLLOWING INFORMATION, IF AVAILABLE.

What is the age for each VAI 65 and over; his/her a) primary diagnosis, b) secondary diagnosis, and c) the illness necessitating ventilator assistance; the unit s/he is on; and as of today, the VAI's time (in days) on ventilator (VLOS), time (in hours per day) on a ventilator (VHRS), expected additional time (in days) on the ventilator (EVLOS), expected payment sources (READ LIST AND CIRCLE ALL THAT APPLY), and if possible, record the proportion paid by the respective sources.

VAI	AGE	DIAGNOSIS	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
EXAMPLE: 66		a) COPD b) Pneumonia c) COPD	ICU	5	4	14	1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
1		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
2		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
3		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
4		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
5		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
6		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
7		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
8		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
9		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)

7. (continued)

VRI	AGE	DIAGNOSES	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
EXAMPLE:	66	a) COPD b) Pneumonia c) COPD	ICU	5	4	14	1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
10		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
11		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
12		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
13		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
14		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
15		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
16		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
17		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
18		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
19		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
20		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)

(IF MORE SPACE IS NEEDED, MAKE ADDITIONAL COPIES OF THIS PAGE.)

8. What, in general, do you think are the major issues in caring for an elderly individual on prolonged mechanical ventilation?

9. Are there any other organizations that you know of that may have data on this population?

Yes ----- (Please give us the name, address and telephone number of the persons to contact for this information.)

NAME -----

ADDRESS -----

TELEPHONE -----

No -----

THANK YOU FOR YOUR ASSISTANCE!

Interviewer

Date

APPENDIX E.

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REGIONAL INSTITUTIONS CASE STUDIES
List of Institutions

Boston University Hospital
Gaylord Hospital
Meriden-Wallingford Hospital
Goldwater Memorial Hospital
Bethesda Lutheran Hospital
Rancho Los Amigos
Creighton University Hospital
Texas Institute for Research and Rehabilitation
Emory University Hospital
University of Wisconsin Hospital
St. Michael's Hospital, Toronto

APPENDIX F.

OFFICE OF TECHNOLOGY ASSESSMENT

VENTILATOR ASSISTED INDIVIDUAL
SURVEY

REGIONAL INSTITUTIONS CASE STUDIES

DATA INVENTORY

The Center for Health Administration Studies at the University of Chicago is conducting a survey of persons 65 and over on prolonged mechanical ventilation for a report by the Office of Technology Assessment (OTA) to Congress. The subjects of this study are persons 65 and over who have required mechanical assistance for breathing (artificial ventilation) at least 4 hours per day over at least a two week time period.

1. Are you able to provide information on these individuals who were patients in your facility for all or part of the period from August 5, 1985 through August 9, 1985?

Yes _____ (Go to question 2.)

No _____ (Please forward this to someone in your institution who can provide this information or call us if it is not available.)

2. In the week from August 5 through August 9, how many Ventilator Assisted Individuals (VAIs) were cared for in your institution?

3. How many of these VAIs are 65 and older?

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4. List the age for each VAI 65 and over, a) primary diagnosis, b) secondary diagnosis, and c) the illness necessitating ventilator assistance; the unit s/he is on; and as of August 16, 1985, the VAI's time (in days) on ventilator (VLOS) in your institution, time (in hours per day) on a ventilator (VHRS), expected additional time (in days) on the ventilator (EVLOS), expected payment sources (CIRCLE ALL THAT APPLY), and if possible, record the proportion paid by the respective sources.

VAI	AGE	DIAGNOSES	UNIT	VLOS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
EXAMPLE:	66	a) COPD b) Pneumonia c) COPD	ICU	5	4	14	1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
1		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
2		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
3		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
4		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
5		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
6		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
7		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
8		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
9		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)

4. (continued)

VP	AGE	DIAGNOSES	UNI	VLUS (days)	VHRS (hours)	EVLOS (days)	PAYMENT SOURCES				
							Medicare	Medicaid	Private Insurance	Family	Other (SPECIFY)
EXAMPLE:	66	a) COPD b) Pneumonia c) COPD	ICU	5	4	14	1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
10		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
11		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
12		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
13		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
14		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
15		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
16		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
17		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
18		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
19		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)
20		a) _____ b) _____ c) _____					1	2	3	4	5
							(%)	(%)	(%)	(%)	(%)

(IF MORE SPACE IS NEEDED, MAKE ADDITIONAL COPIES OF THIS PAGE.)

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5. What is the approximate amount billed per day for the elderly VAIs in your system?

\$ _____

6. In the past month have the numbers of VAIs in your system 65 and over, increased?... decreased?...or stayed about the same? (CHECK ONE)

Increased _____ 1

Decreased _____ 2

Stayed about the
Same _____ 3

7. Do you think that in the next six months the number of VAIs in your system 65 and over, will increase?... decrease?... or stay about the same? (CHECK ONE) Please explain the basis for your estimate.

Increase _____ 1

Decrease _____ 2

Stay about the
Same _____ 3

EXPLAIN _____

8. In your opinion, what are the main reasons for placing an elderly person on a ventilator other than for life-saving purposes? (CIRCLE ALL THAT APPLY)

- a. enable patient to continue a productive life.....1
- b. patient has available support persons to care for him/her..2
- c. patient has appropriate coverage or reimbursement.....3
- d. patient has a reasonable level of mental competence.....4
- e. Other (EXPLAIN).....5

9. In your opinion, what is the most appropriate definition of "prolonged ventilator dependency"?

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10. Are there any other facilities in your area that care for
VAIs?

Yes ----- (Please give us the name, address
and telephone number of the persons
to contact for this information.)

NAME -----

ADDRESS -----

TELEPHONE -----

No -----

11. Please record any additional comments here.

OPTIONAL: What is your: NAME -----

TITLE/POSITION -----

ADDRESS -----

TELEPHONE -----

THANK YOU FOR YOUR ASSISTANCE!

APPENDIX G.

REGIONAL INSTITUTIONS CASE STUDIES
Survey of Ventilator-Dependent Persons by the Massachusetts
Thoracic Society and the American Lung Association of
Massachusetts, June, 1983*

Definition of ventilator-dependency: A patient who required mechanical ventilation for more than three weeks.

Total number of institutions asked to participate: 130

Acute and chronic care hospitals.....120
 Long term care facilities..... 1
 Home care companies..... 9

Response rate: 82.0%

Total number VAIs identified: 147

Age distribution:

Age in years	Total Numbers	Percent (%)
< 1	___9_	__6.1
1 - 15	___5_	__3.4
16 - 53	__35_	_23.8
54 - 69	__50_	_34.0
> 70	__48_	_32.7
Total	_147_	100.0

Type of Institution	Total Number of Patients	Percent (%)
At home	__20_	_13.6
Chronic hospitals	__33_	_22.4
Long-term care facility	___3_	__2.0
Acute care hospital	__91_	_62.0
Total	_147_	100.0

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APPENDIX G. (continued)

Type of Acute Hospital Unit		
General medical-surgical	__38__	__40.0
ICU, CCU or other specialized care unit	__53__	__60.0
Total	__91__	100.0

Diagnoses

	Total Number	Mean Age
1. Chronic obstructive lung disease	__28__	__58__
2. Amyotrophic lateral sclerosis	__18__	__64__
3. Spinal cord injury	__7__	__44__
4. Central nervous system disorders CVA, Intracranial hemorrhage	__12__	__54__
5. Other neuromusculoskeletal disorders	__18__	__41__
Muscular dystrophy...8		
Old polio.....2		
Scoliosis.....2		
Guillain-Barre.....1		
6. Adult respiratory distress syndrome	__6__	__57__
7. Infant respiratory distress	__4__	__--__
8. Malignancy	__6__	__74__
9. Pulmonary infections	__10__	__58__
10. Other	__20__	__58__
Cardiac.....4		

Extrapolation to the entire state of Massachusetts based upon 100% rather than 82% response rate yield 162 ventilator dependent persons. (The population of Massachusetts was 5,767,000, July, 1983 estimate.)

Based on the results noted in the above study the incidence in Massachusetts would be 2.8/100,000.

Applying this same method to the entire U.S. population (233, 981,000, July 1983) yields a ventilator population estimated at 6573.

* These data were contributed by Barry Make, M.D., Boston University School of Medicine and Chairman, MTS Long-Term Care Committee, October 31, 1983. Computations of percentages are by Susan N. Dunne, M.A., Research Project Assistant.

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APPENDIX H.

REGIONAL INSTITUTIONS CASE STUDIES
Study of VAIs in an Intensive Care Unit
of a Canadian Hospital, 1983-1984*

All VAI Patients	Total Number	Percent (%)
On ventilator < 7 days	909	89.3
On ventilator > 7 days	109	10.7
Total	1018	100.0

VAI Patients 65 and over	Total Number	Percent (%)
On ventilator < 7 days	300	86.7
On ventilator > 7 days	46	13.3
Total	346	100.0

* These data were contributed by Robert Byrick, M.D., Director of I.C.U. St Michael's Hospital, Toronto, Ontario.

Care for Life

Contract 533-4935.0

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 4. OUTCOMES OF CARE

October 15, 1985

Prepared By:

Augusta Alba

Robert John Byrick

Allen I. Goldberg

Frank J. Indihar

Gini Laurie

Margaret Pfrommer

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LIFE-SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 4. OUTCOMES OF CARE

A. MEDICAL OUTCOMES

The questions raised by OTA about medical outcomes have been answered by three knowledgeable and experienced physicians with different perspectives:

Dr. Robert Byrick - Critical Care Physician (Anesthesiologist).

Authority on medical outcomes in an acute ICU (St. Michael's Hospital, Toronto, Ontario).

Dr. Frank Indihar - Practicing Internist/Pulmonologist. Innovator of long-term respiratory care unit at a large metropolitan medical center (Bethesda Lutheran Hospital, St. Paul, MN).

Dr. Augusta Alba - Physiatrist/Neurologist. Authority on long-term respiratory care the pioneering Howard A. Rusk Respiratory Rehabilitation Service (Goldwater Memorial Hospital, New York, NY)

Since each original response has had a different emphasis, they are presented in their entirety; the report also incorporates commentary from other physician contributors to this project. The issues are first put into excellent perspective by an extensive review of the literature by Dr. Byrick.

1) Survival Studies (Byrick)

Historically, studies of the medical outcome of intensive care have used mortality as an end-point. The early reports of ventilatory care in special-

ized units (e.g. polio units) were highly successful in saving lives (1, 2). This technology evolved and improved (3) in response to increasingly more complex clinical problems. In extending ventilatory care to groups of patients not previously ventilated, the outcome of this therapy has not been critically evaluated in controlled, double-blind studies. The polio survivors were often young and otherwise healthy, resulting in an invariably impressive outcome.

During the 1960's and 1970's, studies (4,5,6) were performed on the outcome in adults after respiratory failure. The outstanding features of these studies were: 1) the mortality is high in patients with multi-organ failure in spite of respiratory care (25-50% range); 2) the elderly (aged over 65) have a higher mortality rate than younger patients; and 3) prolonged ventilatory care is highly effective for many patients with single organ failure resulting in respiratory insufficiency (e.g. neuromuscular).

Empirical (7) evidence exists that respiratory intensive care in adult cases of respiratory failure decreased both morbidity and mortality in specific disease processes. However, because of the presumed efficacy of ventilatory care by clinicians, no randomized prospective controlled studies have been performed.

In the 1970's, increased health care resources were expended on medical (8) as well as surgical (9) intensive care units. Studies have evaluated costs of care (8,9,10) and the therapeutic interventions (11) used in critically-ill patients. With the increasing complexity of the clinical states treated

in intensive care, a new set of problems made these studies difficult to evaluate. Firstly, many patients, especially in medical ICU studies (12), were never mechanically ventilated. Thus the outcomes of these studies of intensive care do not specifically relate to outcome after ventilatory care. This denotes a change in the clinical concept of intensive care, from a specialized unit concerned with respiratory failure and associated illness, to a unit treating all the critically-ill patients in the hospital. Secondly, these studies (8-12) represent a heterogeneous population of patients with no well-defined disease entity or therapeutic intervention.

This period of systematic investigation, however, was very important, in that clinicians showed that we cannot rely on traditional diagnostic categories to evaluate outcome in complex multi-organ system failure. They also established that the high cost of intensive care in a world of limited resources would necessitate strategies to utilize ventilatory care only in appropriate settings.

Thibault et al (8) documented that only one in ten patients admitted to their medical ICU/CCU setting required a major intervention, suggesting that for the majority of patients, ICU/CCU services were unnecessary. Recent data for survival statistics, by age, after medical intensive care is shown on Table 1 - taken from Thibault (13). The overall mortality rates are representative of studies done in similar intensive care units and exemplify the universal finding that ICU mortality and hospital mortality increase markedly in patients aged greater than 60 years compared to younger groups.

More importantly, Thibault (13) reported 6-12 month survival after medical ICU discharge (Table 2). The follow-up mortality rates were also age-related, being fairly constant up to age 60, then rising abruptly. The cumulative mortality at nine months for patients over 70 years of age was 39% and for patients over 80 years old was 46%.

The outcomes of medical ICU care (13) was also markedly affected by diagnosis (Table 3). It is important to recognize that many of the patients in this list of diagnoses with the lowest mortality rates are never ventilated (e.g. coronary insufficiency, chest pain, syncope, adverse effects of drugs) or require ventilatory support for only a brief period of time (e.g. drug overdose). In the context of prolonged ventilatory care after acute illness, the hospital mortality of patients with such diagnoses as respiratory disease (24.4%), gastrointestinal bleeding (20.0%), sepsis (47.4%), renal failure (23.3%), and cardiac arrest (70.9%) is much higher. This list also serves to indicate some of the major diagnostic causes of respiratory failure and illustrates the difficulty in drawing conclusions concerning the effect of a single intervention such as prolonged ventilatory support from such data.

With specific reference to the elderly, Campion et al (14) studied medical ICU outcome and found older patients were more likely to receive major life-support interventions such as mechanical ventilation, but were less likely to survive. Studies of surgical intensive care outcome have yielded similar mortality figures, with the same limitations.

TABLE 1OUTCOME OF MEDICAL INTENSIVE CARE MORTALITY BY DECADE

Age	Number	ICU Mortality %	Hospital Mortality %
0-19	52	5.8	7.7
20-29	354	4.4	4.8
30-39	375	5.9	8.5
40-49	687	3.6	5.8
50-59	1298	6.3	9.6
60-69	1705	8.4	14.0
70-79	1443	9.7	16.8
80-89	662	13.0	21.8
90+	104	12.5	26.9

Reference: Thibault, GE. The Medical Intensive Care Unit: A five-year perspective. In Major Issues in Critical Care, P. Parillo and S.M. Ayres, eds. Williams & Wilkens, 1984, pp. 9-15.

TABLE 2ICU OUTCOMES: FOLLOW-UP MORTALITY BY AGE

Age	Number	Post-hospital Mortality
0-19	38	5.3
20-29	236	4.2
30-39	237	7.6
40-49	474	7.0
50-59	842	7.8
60-69	1015	12.7
70-79	831	19.5
80-89	389	23.6
90+	62	29.0

Reference: Thibault, GE. The Medical Intensive Care Unit: A five-year perspective. In Major Issues in Critical Care, P. Parillo and S.M. Ayres, eds. Williams & Wilkens, 1984, pp. 9-15

TABLE 3

ICU OUTCOMES: MORTALITY BY DIAGNOSIS

Diagnosis	Number	Post-hospital Mortality	Hospital Mortality
Myocardial infarction	828	12.2	15.4
Coronary insufficiency	650	6.2	2.1
Arrhythmias	441	12.7	6.3
Chest pain	337	4.7	0.2
Congestive heart failure	305	26.6	10.5
Respiratory disease	286	20.6	24.4
Drug overdose	241	5.8	0.6
Gastrointestinal bleeding	181	17.1	20.0
Neurologic disease	92	20.6	19.6
Syncope	91	12.1	1.5
Diabetic syndrome	80	10.0	2.5
Adverse effects of drugs	62	9.7	1.2
Sepsis	54	18.5	47.4
Renal failure	54	20.4	23.3
S/P cardiac arrest	31	12.9	70.9

Reference: Thibault, GE. The Medical Intensive Care Unit: A five-year perspective. In Major Issues in Critical Care, P. Parillo and S.M. Ayres, eds. Williams & Wilkens, 1984, pp. 9-15.

2) Determinants of Survival

In response to the limitations of simple survival studies of intensive care outcome, Knaus et al (15) recognized that a system was needed that would "capture the essence" of what an intensive care unit does. The APACHE system was devised, which stands for Acute Physiology and Chronic Health Evaluation (16). The acute physiology score (APS) of APACHE is a relative value scale assigning a weight (0-4) to each of 13 common physiological parameters that describe the function of the body's major organ systems. This index (APS) has been validated (17), and there is a smooth and consistent relationship between APS on admission and risk of death. This relationship has been verified in multi-centre trials in the U.S.A. (18) and France (19).

A major finding in the series of studies which have been summarized by Knaus (15) was that there are five major potential factors determining outcome of intensive care (and ventilatory care). These factors are particularly relevant to the outcome of care in the elderly. The APS represents the degree of physiological disturbance of a particular disease process; the elderly are considered to have a reduced physiologic reserve. Knaus' studies suggest that acute physiologic abnormalities have the same implication in terms of risk of death regardless of the disease process initiating the physiologic disturbance. In the elderly, outcome should be assessed in terms of APS rather than the traditional diagnostic classifications as discussed in Part 1 (Survival Studies).

Because Knaus' studies are so important, each of the five determinants of outcome will be discussed independently with special reference to the el-

derly: a) type of disease process, b) severity of disease, c) chronic health status, d) age, and e) therapeutic modalities available.

a) Type of Disease Process

There is no doubt that the type and the reversibility of the primary disease process precipitating ventilatory care determines outcome. For example, cancer patients have a higher mortality rate than other respiratory failure subjects. Patients with irreversible disease processes, such as severe pulmonary emphysema or end-stage ischemic heart disease, occasionally cannot be weaned from ventilatory support in acute care hospitals. Patients with irreversible disease processes requiring ventilatory support are the subject of this OTA report. Therefore, it is important to emphasize that these patients are a vast minority of the total group of patients treated with prolonged ventilatory support. It is equally important to emphasize that these patients with irreversible disease processes are extremely difficult to predict "failure to wean" prior to instituting initial ventilatory care. This issue - prognostic uncertainty - is the crux of the physician's dilemma in the decision-making process which will be discussed in OTA Task 5.

Multi-organ failure in a patient treated with ventilatory support also increases the risk of death (21). This study (21), and our published data (Appendix), suggest that unless organs system failure are reversed quickly (less than 2 days), the hospital mortality rate exceeds 50 percent. None of the 90 patients with three or more organs system failure for more than 2 days left hospital alive. Our experience in the elderly (Appendix)

specifically suggests that the combined effect of renal and respiratory failure is a very high probability of death. These data must be noted to emphasize the difference in patient populations between those treated today in intensive care and polio patients treated in the 1960's (1,2). The potential for long-term salvage of large cohorts of patients was very high during the polio epidemics. Single organ failure (respiratory) was specifically treatable by mechanical ventilation (hence reversible) in younger people.* In contrast, patients treated with prolonged ventilatory care in ICU today have severe, irreversible disease, often coexisting with multiple organs system failure in elderly people.

b) Severity of Disease Process

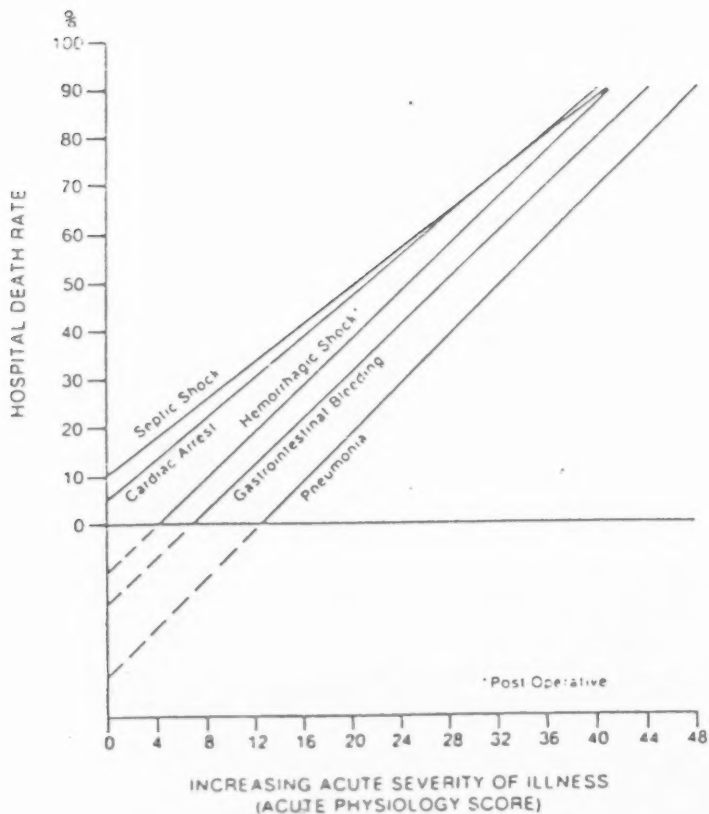
If severity is analogous to APS, then the probability of death increases with increasing severity as shown by Knaus et al (15).

This relationship is also true for a variety of primary disease processes (Fig. 1).

*Editorial Comment: The polio patient had acute respiratory failure because of involvement of the neuromuscular system; there was no primary problem with the lungs. The same good outcome has been the experience with other medical conditions which involve the neuromuscular system. I agree that the pathophysiology is a very important prognostic factor. Controversy exists regarding which kinds of pathophysiology is appropriate for prolonged mechanical ventilation. (Goldberg)

FIGURE 1

EVALUATING MEDICAL SURGICAL INTENSIVE CARE



OLS Regression
All slopes significantly ($p < .01$) larger than zero

Relationship between severity of illness and hospital death rates by disease.

Reference: Knaus, WA., Draper, EA., Wagner, DP. Evaluating Medical-Surgical Intensive Care Units. In Major Issues in Critical Care, P. Parillo and S.M. Ayres, eds. William and William, 1984, pp. 35-59.

We investigated the influence of severity (APS) specifically in very elderly patients (75 years of age and older) who required ventilator care in our respiratory intensive care unit (RICU). This experience is fully described (Appendix) and has been accepted for publication in Critical Care Medicine*. The major findings are as follows:

- 1) The APS on RICU admission could not predict survival.
- 2) Only 17.9% of these elderly patients died in hospital (11.5% in RICU).
- 3) This mortality rate was higher than in younger patients.
- 4) Hospital survivors were not only from the low-risk monitored group or after elective surgery; that is, age and APS cannot predict outcome, and the dilemma of prognostic uncertainty in the outcome of ventilatory care for the elderly remains.

c) Age

Knaus' studies have identified age as an independent risk factor, presumably related to reduced physiologic reserve to a given disease process. A study in the very elderly, however, suggests that many critically-ill patients over 75 years of age do benefit from RICU care, including in-hospital prolonged ventilation. Very few - if any - of this age group could function independently if confined to a ventilator-dependent lifestyle. None of our patients received any ventilatory support outside of the RICU. There may

*Byrick's study has been since published: McLean, R.F., McIntosh, C.D., King, G.Y., Leung, D.M.W. and Byrick, R.J. Outcome of respiratory intensive care for the elderly. Critical Care Medicine 8:625-9, 1985.

be some elderly patients (aged 65-75) who could benefit from a home ventilatory support outside of RICU. These patients are rare among the large groups studied in RICU environments of acute care hospitals.

d) Chronic Health Status

The elderly have a higher prevalence of chronic debilitating disease processes, which is a major factor limiting physiologic reserve and their capacity to live independently in a home-like environment. This emphasizes that age alone is NOT a factor or criterion on which we should limit the use of mechanical ventilation. Individualization of patient care planning is essential for long-term ventilation - whether in RICU or in a home care program. Many of the patients treated in RICU with prolonged ventilation have chronic debilitating diseases or irreversible disease processes that would make them inappropriate candidates for a home care ventilation program. Several authors (14,15) have noted a slight trend toward fewer RICU admissions above age 70. Campion (14) suggested that physicians may be less aggressive treating acute problems in elderly patients; however, this may reflect the influence of chronic health status on overall decision-making. This will be discussed further under Task 5 of the OTA report.

e) Therapeutic Modalities Available

Physicians have been urged to "contribute more by doing less". There is no doubt that survival is not linearly related to resource utilization. In fact, Scheffler et al (22) have identified a U-shaped relationship between increasing therapy and the probability of death. The ethical aspects of the application of technology (ventilation) to the elderly is particularly

troublesome to the clinician. Simply because the technology is available, physicians should not feel compelled to utilize it inappropriately. Studies (23) show that a disproportionate amount of health care expenditures occur in the last year of life. The increase in the use of hospital care in the last year of life did not begin in the USA recently, but in the mid- to late 1960's, after the introduction of Medicare and Medicaid programs. This suggests that availability of the technology may be a factor. There are no data that I am aware of which suggests this trend inappropriate for the severity of illness. Scitovsky (23) suggests that the increase in resources used in hospital (including ventilators) has been proportionately the same for patients who die and those who survive.

CONCLUSION

The detrimental physiological effects of prolonged ventilation are minor, and most patients adapt spontaneously to respiratory support. The implications for elderly patients' prognosis will largely depend on such factors as the reversibility of the primary disease process, severity of illness, and chronic health status as described. Our study (Appendix) suggests that in-hospital prolonged ventilatory support can result in elderly long-term survivors who live independent lifestyles that they consider satisfactory.

The rates of recovery from specific disease processes vary with associated factors, especially severity of illness. In our own experience, very few elderly patients who are ventilated long-term in RICU are candidates for permanent ventilation.

3) Physiologic effects of mechanical ventilation; prognosis, need for further care (Goldberg, Indihar)

Patients who require mechanical ventilation generally fall into two major categories:

1. Those who can reasonably be expected to be weaned from ventilation.
2. Those who cannot be reasonably expected to be weaned for mechanical ventilation once it has been applied.

The physiologic effects will be different according to the category. In those anticipated to be weaned, mechanical ventilation is used to reverse acute single or multiorgan system failure and to "buy time" for this to happen. When oxygenation and ventilation are improved, the brain is preserved, and the heart, kidneys, and other vital organs improve their function. This improved function permits a more rapid recovery from the acute illness and return to previous health. In those not anticipated to be weaned, mechanical ventilation is used to augment or replace natural efforts to breathe. Under these circumstances, improved oxygenation and ventilation will enhance mental function (increase clarity of thought, level of awareness, state of alertness) as it improves the function of other vital organs. One result of ventilatory treatment is an improvement in mental competence which is due to improved gas exchange that was not the case during ventilatory failure. The physiologic result of such use of the ventilator is a more medically stable patient who requires less diagnostic intervention or major changes in therapeutic management. Such a patient is then a candidate for transfer to an alternative location with less costly technology and caregivers. It is possible that with more time and rehabilitation, such a person may also improve to the point that they may

become free of life-supporting technology. This would result from a period of medical stability that was made possible by prolonged mechanical ventilation.

Not all physiologic effects of mechanical ventilation in the elderly are clear-cut. Persons with advanced age are always at risk for complications of their basic disease. The use of a ventilator predisposes a patient to immobility; this increases the risks of phlebitis and embolization. With chronic ventilator use, the return of blood to the right side of the heart is impaired; this can lead to chronic right heart failure. However, this effect is balanced by improved pulmonary blood flow due to reversal of hypoxia and hypercarbia.

The prognosis and need for further care will also depend upon the category. For example, a younger adult, with a high cervical cord transection, resultant quadriplegia and ventilator-dependence, cannot be reasonably expected to ever be weaned from mechanical ventilation. This is similarly true with progressive neurological diseases and some patients with severe chronic obstructive pulmonary disease. Most patients with acute respiratory failure are considered to be "weanable"; the ventilator is utilized as a temporary measure. Later, it may be discovered that, due to the patient's underlying disease process (severe emphysema, lung fibrosis), weaning is impossible. In both categories, consideration of ultimate outcome must be considered before application of the ventilator. However, in most instances, the prognosis is virtually impossible to predict, particularly in the

emergency situation where the ventilator is applied as a short-term necessity and, unfortunately, the patient subsequently is not weanable for one reason or another.

The prognosis depends upon the disease process. Younger patients with high cervical cord injuries, quadriplegia, and ventilator-dependence will have a virtually normal life expectancy. However, the patient with chronic obstructive lung disease, emphysema, and ventilatory failure requiring ventilator assistance will more likely be elderly and have other disease processes expected with age. Generally, most of the patients who require mechanical ventilation will have a significantly shorter life expectancy than their non-ventilated counterparts; however, many of the patients residing on the Prolonged Respiratory Care Unit (PRCU) at Bethesda Lutheran Medical Center, St. Paul, Minnesota, have been ventilator-dependent for 4-5 years. Patients with neurological degenerative diseases (amyotrophic lateral sclerosis) gradually succumb to the ravages of the primary neurological disease process and not to the respiratory failure which initiated the ventilator support. These patients often live for 2-3 years once the ventilator has been applied.

4) Rate of survival, death; dependency on mechanical ventilation; degree of dependency (Indihar)

The experience from the Bethesda Lutheran Hospital PRCU indicates that 35.5% of the patients died while on the unit; other patients have been discharged to other care facilities and have died there. (See OTA Task 2: Rehabilitation Statistics from the PRCU). Such patients were, for the most part,

elderly, with chronic fibrotic and/or obstructive lung disease, who suffered from irreversible disease processes. Ventilator-dependent elderly survivors were virtually unweanable and remained dependent on mechanical ventilation regardless of the efforts of staff and patient. The underlying medical condition was generally too severe to be alleviated through normal weaning techniques. Also, the majority of these patients were usually ventilator-dependent 24 hours per day. Small incremental periods off the ventilator could be achieved; perhaps the patient could even be off the ventilator in rare instances for waking hours. However, the ventilator was, at a minimum, required at least 12 hours per day in virtually all instances. Indihar's elderly survivors often had an elderly spouse and no other primary caregiver available. Thus, existence out of an institutional or communal living situation was very difficult to achieve, but not totally impossible, given an adequate home care support system. The most essential requirement was a non-professional, personal care attendant who worked under the supervision of health care professionals.

5) Impact on functional ability (Indihar)

If the patient remains on a stationary (console) ventilator, ventilator-dependence virtually immobilizes the patient. Logistical constraints (the tubing) prevent any more than the most limited activity (i.e. moving from the bed to a bedside chair or commode). Of course, the patient can be placed on a portable ventilator, which is quite mobile. This device can be placed on a small table, or moved from place to place on a specially-built rack which is part of a manual or patient-driven electric wheelchair.

Portable ventilators cannot be used as the primary ventilator, because there are insufficient alarm capabilities, and humidification cannot be readily adapted to these machines. But if the patient is under close observation by another person, the portable devices are quite safe for short periods of time (i.e. up to 4-5 hours), thus permitting mobility and a wide variety of activity.

Acute respiratory failure is a life-threatening situation; mental function is not appropriate or reflective of the patient's fullest potential. In addition, this is an emergency when decisions must be made with a great deal of prognostic uncertainty. With chronic respiratory insufficiency, mental competency is difficult to judge in patients, whether ventilated or not, who are hypoxic or hypercarbic, particularly those with chronic obstructive lung disease. Although each individual tends to respond in a unique way, even hypoxia (lowered O_2) or hypercarbia (elevated CO_2) to a mild degree tends to decrease mental functioning and decision-making. However, such hypoxia and hypercarbia can be reversed by optimal ventilation and supplemental oxygen often with an improvement in mental function. According to Indihar, the mental competence of an elderly, ventilated patient is generally not unlike what would be seen in a non-ventilated person of comparable age, particularly when the patient is "stable" and not suffering from complications of a disease process (pneumonia, bronchitis, cardiac failure) which, by causing a fall in blood oxygen level, could result in confusion and even coma. It has always been Indihar's policy to allow the patient to make as many decisions concerning their own life as possible. Although judgment is sometimes impaired, Indihar has not found it to be that much different from any other chronically-ill patient, young or elderly.

6) Technology: safety and risk (Indihar)

According to Indihar, ventilators are quite reliable, given a reasonable maintenance schedule*. Battery backup in the event of electric failure is available for all portable ventilators, and replacement ventilators** are generally immediately available from reputable home care providers within a short period of delivery time. Likewise, compressors, humidifiers and other ancillary pieces of equipment are quite basic pieces of machinery, and, with adequate maintenance and replacement schedules, can be expected to perform reliably.

The sources of oxygen have generally been considered to be the most dangerous piece of equipment located in the patients room, particularly if the patient is not in a institutional setting where the oxygen source is likely piped in through the walls from an external bank. There are potential risks of inflamability, leak, or explosion from gas under pressure if the tank is not handled properly. Most patients and their families dislike the concept of a large and dangerous oxygen tank in their home. However, given proper precautions, these tanks are quite safe.

*Although routine maintenance is done, there has been an increased incidence of sudden equipment failure in my own experience and in that of physicians, respiratory therapists, and consumers with whom I network. This matter has been brought to the attention of the ASTM, F-29 Committee. (Goldberg)

** Depending upon the medical conditions, it is necessary to prescribe more than one ventilator because of life-threatening risk of sudden equipment malfunction. I have not found that having this ventilator out of the home to work out satisfactorily. (Goldberg)

7) Medical Outcomes at Goldwater (Alba)

Goldwater Memorial Hospital in New York City is a 910 bed facility, which has specialized in long-term rehabilitation and treatment of chronic illness.* As a regional referral center for rehabilitation, the kinds of patients are different from that in the acute general hospital. Goldwater accepts patients with chronic conditions from the Greater New York Metropolitan Area and beyond.** Ten percent of Goldwater's patients have tracheostomies, and 16% require tube feeding; both categories usually stay at Goldwater for the remainder of their lives. A large majority of the patients who are admitted to the ICU for acute intercurrent illness from other areas of the facility (Skilled Nursing, Rehabilitation Medicine, Long-term Medicine) already have moderate to severe cognitive impairments. It is the impression of the Director of Intensive Care that, excluding patients with COPD, approximately 1/3 of the patients admitted to ICU for mechanical ventilation will survive.*** Approximately 50% of these survivors will remain on prolonged mechanical ventilation for an undetermined length of time. The majority do not return to their baseline physical and mental functioning. The data on the exact number of individuals who were admitted to the ICU as ventilator-users, or who became ventilator-users in the ICU and then died, will be obtained for OTA Task 3.

*Medical outcomes of patients at Goldwater are also discussed in part in OTA Task 2 (Description of range of patients).

**At any one time, there is a 50-75 patient waiting list to enter Goldwater by similar ventilator-users from the acute hospitals in the Greater New York Metropolitan Area.

***There are approximately 200 deaths annually at Goldwater; 50% of them occur in the ICU.

For patients who are maintained on long-term ventilation primarily because of either chronic intrinsic lung disease or neuro-muscular-skeletal diseases, the prognosis is quite favorable. The COPD patient may go in and out of ICU several times during their stay at Goldwater. They may be weaned, or partially weaned, again and again, depending on intercurrent infection and other factors such as concurrent medical illnesses. The majority of COPD patients at Goldwater must remain there; they are over 65 years old, mentally competent, and lead a satisfying life within the rehabilitation milieu the hospital provides.*

Our Chief Pulmonologist estimates that the lifespan of the COPD patient following admission to Goldwater with advanced disease is anywhere from 1-10 years. (Very complete statistics will be provided for OTA Task 3). The majority of these patients are capable of partial self-care. In addition, there are approximately 35 patients with neuromuscular disease at Goldwater in the Howard A. Rusk Respiratory Rehabilitation Service. The majority will survive an admission to the ICU with cognitive abilities intact. About

*"Most patients from the senior citizens group who need or are on mechanical ventilators are mentally intact and WANT TO LIVE. They have had productive life in earlier age. They have paid taxes, built the prosperity of this country, raised family, paid for the education of the younger generation and have served their country in many ways. It will only be fair that their fellow men give them the chance to live as long as they enjoy life, even if they are on mechanical ventilation." "My 9 COPD patients are alert and bright and, in the past, were professionals. Unfortunately, they either have no family, or their families fear taking them home or caring for them. There are no health related facilities or nursing homes which are equipped to take care of patients on respirators" (Lilia C. Gay, M.D., Attending Physician, Department of Medicine, Goldwater).

15 ventilator-users per year from this Service are able to return to live in the community, either with family, or independently with the assistance of paid caregivers. The number of ventilator-dependent patients with neuromuscular disease who are 65 years old and discharged to the community is less than one/year.

The elderly patient has characteristics of the lung that increase risk for infection. Specifically, the closing volume (volume at which small airways tend to critically narrow or collapse) becomes smaller with age. If the elderly person has increased mucous (bronchitis, COPD), or reduced strength (neuromuscular weakness), secretions may be retained and cough impaired. These secretions must be mobilized and removed or they will lead to further collapse of segments of the lung and infection. If the elderly person requires prolonged mechanical ventilation, proper upper airway management (chest physiotherapy, suctioning) will be essential to clear these secretions. The prolonged use of a ventilator in the proper way will expand the lung and reduce the likelihood of infection. There is no reason to anticipate an increased risk of infection with time because of the ventilator per se. However, the risk is increased from antibiotic-resistant bacteria which are more likely found in an institutional or nursing home setting.

There is no critical moment or duration of time beyond which risks of prolonged mechanical ventilation increase or change provided that all involved are well aware of the techniques and technologies involved. In fact, risks are less because the patient is more medically-stable. However, there is a risk with the long-term ventilator-user (10% vital capacity and

requiring ventilation 24 hours/day) of anoxic encephalopathy occurring during inter-current massive respiratory infection, or during resuscitation from inadvertent cardio-pulmonary arrest. Such patients may not be rendered brain dead by these insults, but may remain either in a semi-comatose or comatose condition for many months or even years. With the law as it stands today, such patients must be maintained on ventilators until death from other causes. It is the feeling of medical staff at Goldwater that the use of mechanical ventilation to prolong death rather than to sustain life in such situations is an abuse of technology.

Portable ventilator equipment is rapidly becoming more sophisticated. Many elaborate alarm systems have proliferated, and with proper maintenance, these devices are becoming safer in the home.* Staff must constantly reassess the types of ventilators being used by each patient. Multiple factors must be taken into consideration. It is recommended that the Bio-Ethical Committee of the Medical Board take an active role in working with the medical staff on these issues. Risks are greater outside the ICU, but the lifestyle of the individual is eminently more satisfactory, unless requiring an ICU for critical illness. The patient, where possible, himself must be actively involved in decision-making on the type and number of ventilators and alarms.

*As a student of Dr. Alba and frequent visitor to Goldwater, I must state that the major reason why this equipment is safer there is because it is used and maintained by a center of expertise. (Goldberg)

B. SOCIAL, PSYCHOLOGICAL, ECONOMIC OUTCOMES

The questions raised by OTA about social, psychological and economic outcomes have been answered by three expert authors with multiple perspectives:

Dr. Robert Byrick - Authority on outcome analysis in an acute ICU

Margaret Pfrommer - A ventilator-dependent adult for over thirty

years; an authority on technical aids (Department of Rehabilitation Engineering, Northwestern University Medical School); and President, Illinois Congress of Organizations of the Physically Handicapped (COPH)

Gini Laurie - Editor, Rehabilitation Gazette and Founder, Gazette

International Network Institute. An authority on independent living for disabled persons and the resource person for over a generation regarding prolonged ventilation issues.

Due to the nature of the responses, they are presented according to perspective. In addition, comments from other authorities have been included to assure a balanced discussion.

Psychosocial Outcomes (Byrick)

There is little data in the medical literature on the effects of prolonged ventilator care on the psychosocial adaptation of elderly patients and families. Subjective studies by Campion et al (14) and ourselves (24) suggest that elderly patients who have survived prolonged ventilatory support during critical illness in hospital can function as well in society as younger patients. In an effort to specifically examine this issue in an

elderly population (greater than 75 years of age), we asked survivors if they would undergo the same treatment again. The vast majority of these patients wanted aggressive ventilatory care if confronted with similar circumstances (Appendix). This suggests that prolonged ventilatory care by itself is not uncomfortable nor particularly distressing from a psychosocial adaptation point of view.

The major psychological factor to stress is that prolonged ventilatory care could cause a failure to confront death when it is inevitable. In these circumstances, irreversible disease processes, which ultimately will lead to death, could be treated (inappropriately) by mechanical ventilation and associated supportive techniques with no hope of achieving an independent individual. Such situations must be minimized to reduce the negative impact on patients and families who must confront the decision to "let death come". This inappropriate use of prolonged ventilation is primarily an in-hospital issue at this point in time. The primary causes of employing life-supporting technology in circumstances where it is "medically useless" (25) may be a combination of such factors as:

- 1) physician attitudes,
- 2) legal uncertainties re: responsibility,
- 3) resource availability,
- 4) medical inexperience,
- 5) prognostic uncertainty,
- 6) lack of "withdrawal of care" protocols, and
- 7) patient "informed consent" issues.

These issues are particularly troublesome in the critically-ill where existing data cannot predict outcome with certainty. One urgent need is for education of both medical and lay communities concerning realistic expectations from medical care.* Although survivors in our study considered RICU care worthwhile, we cannot estimate the psychosocial harm inflicted on the patients who died by prolonged ventilatory care.

In a general open-ended questionnaire, we assessed the ability of survivors of RICU care to function in society (24). Their level of social activity was satisfying to them, and most were functioning at a level comparable to their pre-morbid status. This is particularly important in the elderly population, as they were not fully active and independent (Appendix). Since most of these patients had chronic health problems before an acute exacerbation or illness, the most important factor was that they believed that this level of activity was worthwhile and satisfying.

Make et al (26) and Goldberg (27) have documented similar psychosocialization of patients to a chronic ventilator-dependent lifestyle. I have no experience with this type of patient, but can only emphasize that very few of our elderly survivors could independently care for themselves if ventilator-dependent. Hughes (28) has stressed some potential problems with a home-

*Such an effort is currently underway by Sister Corrine Bayley, CSJ, Director of the Center for Bioethics, and Vice-President, St. Joseph Health System, Orange, CA. In the project, California Health Decisions (Involving Citizens in Health Care Choices), at "town hall meetings", the questions are asked, "Are we obliged to prolong life with every means at our disposal? If not, when should we stop? Who should decide? (Appendix)

ventilation program. By extending such resources outside of the RICU environments, the health care delivery system is also extending the potential for psychosocial maladaptation and extending harm.

If the resources are widely available in a relatively unsupervised format by inexperienced clinicians, there will be individual cases where the technology is applied inappropriately. This will be costly from an economic point of view, but the greatest harm may be in extending unrealistic expectations within society. This emphasizes the conclusions of Goldberg (29) that regional centers should be established with well-organized support staff.* By using the regional system approach, the selectively small number of elderly patients who can benefit from a home ventilator program could be followed and such psychosocial factors as depression and suicide could be minimized.

Economic Outcomes (Byrick)

The medical literature is replete with data verifying the fact that prolonged intensive care (including ventilatory support) is very costly to the health care delivery system (4-8). In a preliminary study done in our RICU, 80 per cent of the non-physician costs were salaries. This emphasizes the need for sophisticated nursing care and respiratory technologists to support mechanical ventilation in intensive care settings.

*Such centers provide many other benefits including quality-assurance, case-management, care-monitoring, and cost-savings. (Goldberg)

An instructive study was performed by Detsky et al (30) who showed that the most expensive admissions to ICU were those with unexpected outcomes. This emphasizes that the cost of ventilatory care in-hospital is directly linked to the issue of prognostic uncertainty which has been discussed previously. Cost-containment policies for ventilatory care require better prognostication by clinicians to limit provision of these expensive resources to patients who can truly benefit from such care.

The cost of long-term ventilation outside of RICU settings is substantially less than that documented in RICU. However, one must recognize that increased provision of home ventilator programs will not substantially reduce health care costs in acute care hospitals (31). The majority of ventilator-dependent patients in acute care hospitals are not candidates for a prolonged ventilatory dependent lifestyle. This is particularly true of the elderly subgroups who have a high incidence of significant co-morbid conditions necessitating care in RICU settings (for example renal insufficiency, dementia etc.). These disabilities would make independent living with a ventilator improbable.

Although the direct costs of a home ventilator program to acute care facilities will be less than RICU care, such indirect costs to the health care system as home visits by nursing personnel must be considered. There may also be economic costs to families in terms of lost income, and living

space in the home. These factors will be discussed in detail by other contributors to the OTA report who have experience in this area.*

3) Social, Psychological, Economic Outcomes - The Consumers' View

(Pfrommer, Laurie)

"Over the next 50 years, the Census Bureau projects that the number of Americans 65 and over will more than double from 26.8 million to 65.8 million. As a result, programs designed for senior citizens could comprise as much as 65 percent of the federal budget compared with almost 28 percent today....Key issues over the next 50 years will involve housing and health care. Even with medical advances, a segment of the population, especially those over 85, will have disabling diseases."(32)

As noted in OTA Task #3, a small number of elderly persons will require either temporary or long-term mechanical ventilation. These elderly persons may include some who are previously in good health, some with simple or complex acute and/or chronic health problems, and even those with

*There is an increased utilization of energy; electricity and heat is used around the clock for equipment and/or needs of caregivers. Often, there is an increased tax-assessment of a house which has required modification for increased living or storage space. Some situations require modifications of the dwelling and/or transportation vehicles for assessability and/or health needs (e.g. a van may be required for assessability to health care). All of these represent costs which are health-related but not directly reimbursable. Thus, they represent indirect costs which add to the burden of 1) high co-payments requested of families and 2) less than comprehensive reimbursement by public agencies and private insurance. Most families do not have the money to pay for these indirect costs of home care. (Goldberg)

terminal illnesses. If an elderly person needs this support in an acute situation, and they do not receive it, they will not live as long. If they do survive, they will not be as alert and sensitive to their surroundings as they could be, and their physical condition will deteriorate much more rapidly than that of those who enjoy the benefits of sufficient ventilation.

There are many issues that our society has to face in regard to this population: Is this population (of which any one of us may become a part) worthy of our special attention? Is it important to have a Grandma, even if she is on a ventilator? Are the experiences of a wheezing old man beneficial to the young man? If these persons are of value, then we must muster all resources to enable such elderly persons to have at least a minimal quality of life.

Life-supportive technology has saved and prolonged the lives of many people of all ages only to relegate them to acute care hospitals or nursing homes; only a few have had the opportunity of the transition to home, a congregate housing arrangement, or hospice program. The challenge created by persons who require prolonged mechanical ventilation is one of providing more of them with options which will consider their safety, their need for individual life styles, and a comfortable death with dignity. The following case history dramatically demonstrates how this can be done:

A 70 year old female first visited her pulmonologist in December, 1979. She was a retired school teacher with a history of severe, slowly progressive chronic obstructive pulmonary disease. From 1979 to April, 1984, she had a protracted and steadily progressive illness. Despite optimal medical management which included home oxygen, she continued to deteriorate. The patient lived with her son, daughter-in-law, and their 4 children. She had 3 other children, and many grandchildren. Despite her physical

impairment, she had a good quality of life in her loving environment.

The patient had made it quite clear to her pulmonologist and family that she did not want ever to be kept alive by heroic or artificial means; specifically, she did not want to be on a respirator. On 4/1/84, she was admitted to the hospital ICU with pneumonia. She was severely hypoxic with PO_2 in the 40's despite all therapeutic efforts. The pneumonia progressed; she got weaker, had more trouble with secretions, became extremely short of breath. Smothering, she could not rest and was very uncomfortable.

A consultation was held with the family. They were told that all was being done; there was nothing else to do except intubation and mechanical ventilation. The patient had stated her objection to this. The family had a lot of difficulty watching the patient fight for breath. They asked about the reversability of the disease and likelihood of getting off the ventilator. They were told that pneumonia was potentially reversible, but that the inability to wean was a possibility. They requested that the pulmonologist talk to the patient.

Despite the fact that the patient was hypoxic, she was alert and fully comprehensive of what was happening. The situation was fully discussed. Because of extreme discomfort and shortness of breath, she accepted the slight chance that her pneumonia could be cleared and she could be weaned; she elected for mechanical ventilation.

Subsequently, a prolonged hospital course ensued. Despite efforts at optimal ventilation, antibiotic and bronchodilator therapy, pastoral and psychological counselling, and a variety of weaning strategies, the patient was unweanable. The patient was now considered on prolonged mechanical ventilation, and home care was entertained.

Because of an excellent home environment with people who were loving and willing to care for her, the patient was sent home. Her care was provided by family members and sitters brought in by her family to supplement their efforts. On occasion, the patient had physical therapy and the consultation of mental health counsellors and home care nurses.

Living in her own specially-adapted room, the patient's interest in life returned. She spent much time with children and grandchildren, celebrating all holidays with her loving family. She began reading again, listening to music and watching TV. She resumed interest in her business holdings, and began again to plan her own affairs.

The pulmonologist made many home visits. He observed her spirit and the quality of life she was enjoying. Once, he brought a

pessimistic member of the Board of Directors with a special interest in geriatric and medical ethics. After the visit, the Board Member commented about the patient, "She is radiant!"

On 2/9/85, the patient passed away in her sleep. This was 9 days short of 8 months at home. This period at home was one of quality, love, and involvement in her surroundings.

There is one case-example in our society which presents evidence that prolonged mechanical ventilation is appropriate and acceptable. The ventilatory experiences of individuals disabled by respiratory poliomyelitis encompass both those who have been users for more than 30 years, and those, weaned years ago, who are now returning to ventilatory assistance at night to compensate for decreased respiratory function due to aging as they approach the status of senior citizen (39). With some exceptions, the former polio survivors on mechanical ventilators have lived at home with their families since the early 1950's when they acquired polio as children or young adults. The majority are employed and pay taxes. They are married and have children and grandchildren. They buy homes and cars. They travel. They have been their own case-manager and have assumed ventilator maintenance. Their lives are proof of the potential of ventilator-users to live fully and productively in their communities if they have adequate support systems (39)*.

*My personal physician is such an individual. In his late '50's, he practices medicine full-time and has done so for over 30 years. He uses mouth intermittent positive pressure ventilation in his office practice and sleeps at home or during travel to medical conferences in an iron lung. I have chosen this physician because he has taken the time to keep up his education and he listens. (Goldberg)

The following case history illustrate one woman's adaptability and potential:

E.T.H., Artist, ballet teacher, and choreographer. Now in her early 60's, she has been a respiratory polio quadriplegic since 1953. A former Sadlers Wells ballet dancer, she teaches ballet and liturgical dancing with the assistance of a remote-controlled tape recorder and portable voice amplifier. She paints with the brush held between her teeth. During the day, she uses glossopharyngeal breathing and works in her own home with the help of attendants. At night, she returns to her iron lung in a nearby hospital.

Her situation, as well as that of many other polio survivors, demonstrates that persons on long-term mechanical ventilation have not only survived, but have thrived, in settings outside of hospitals and nursing homes. By their learning experiences, we have been able to determine that (1) they had a safe transition to home, (2) their living has been less costly than in institutions, (3) they have needed some kind of community service support, and (4) they have exhibited a variety of life styles.

The same resilience and self-direction of their own lives is demonstrated by ventilator-assisted individuals with myasthenia gravis, high-level spinal cord injury, amyotrophic lateral sclerosis, muscular dystrophy, and other neuromuscular diseases. The following case history illustrates this adaptability and potential:

Q.G. Retired executive and gentleman farmer. In his mid-60's, he has been disabled by amyotrophic lateral sclerosis for more than eight years. He is dependent upon a ventilator full-time. He lives at home with the assistance of his wife and a daytime nurse. They travel in their specially equipped motorhome.

Does this positive experience for over a generation with prolonged mechanical ventilation of these survivors of polio and other neuromuscular disease have relevance to issues facing an old person? The answer is yes. According to Make, the patient with neuromuscular disease comprises the majority of long-term ventilator users; there are very few centers with programs dealing with COPD, and they are represented in this OTA survey. If an elderly person requires prolonged mechanical ventilation, the above experience relates that this can be accomplished and what is needed to do so (medical stability, an acceptable social situation, an appropriate environment, sufficient support services and funding). As Byrick stated, the older person with multiple system vs. single system involvement will not achieve this stability or likely survive. However, if they do, the needs become less medical and social. The older person is less likely to have family members who can serve as caregivers, and they may need non-professional personal care attendants in order to function in activities of daily living. This was exactly the problem that faced the polio survivor of the '50's as a young adult. It is of great value to analyze the system that was put in place for such patients, for such a system is needed again today for young and old alike. (39)

The negative impact for prolonged mechanically ventilated persons living in hospitals or nursing homes applies regardless of age. Care in a hospital setting is highly-skilled, but the environment as a whole intrudes upon the

privacy and dignity of the individual. The most significant difference between institutional living and home care, as stated by former patients in both hospitals and nursing homes, is that when persons enter institutions, they come under rules and regulations that do not allow them to direct their own care. They lose control of their lives. "This atmosphere is noisy...and the patient is subjected to frequent interruptions of sleep cycles. The most extreme example of depersonalization in the intensive care unit is the isolation of ventilator-dependent patients whose airways become colonized with nosocomial pathogens dangerous to other patients". (33)

Sometimes families are discouraged by caregivers (physicians, nurses, social workers) who lack a positive concern for the right to a life of choice of the ventilator-dependent person or a lack of understanding about alternative life styles, feelings, and values. These personnel, of which the chief decision-maker is the physician, are almost totally influenced by the rules and regulations of the organizations for which they work or those of the reimbursement agencies. Furthermore, doctors do not always know who are good candidates for long-term ventilation. It is relatively easy to prescribe a respiratory program for persons with an acute decompensation, but it is more difficult to deal with the chronically-ill who have used ventilator equipment for years, those who have not used it for a long time, and those who have never used it. For these people, the medical professionals need more awareness about these categories of respiratory care.

A spokesperson for the Hastings Center stated on network television that the elderly are living longer lives, but not better. The emphasis in medical

care in our society is on acute care, with little regard given to those with chronic conditions. Because of this emphasis, the potential is very great for improving their quality of life and that of those who are terminally ill. Presently, they are too often "dumped" into long-term care facilities (nursing homes).

Nursing home staffs are usually poorly trained, and the number of personnel is inadequate to provide the individual care needed to ensure safety. A person with emphysema requiring treatments four to six times a day would not be readily welcomed in a nursing home; the monopoly of staff time would penalize the other patients needing attention. A good program of home care far surpasses any care given by a nursing home staff. For example, a ventilator-dependent man in a nursing home complained that the emergency alarm on his ventilator rang for twenty minutes before a member of the staff responded, and then not because the staff member knew what the alarm meant, but because the noise was irritating. It is not very likely that such ignorance would occur in a home-care situation. If it is thought that the lives of persons requiring full-time mechanical ventilation will be better ensured in a nursing home, there is repeated evidence to disprove this. The Subcommittee on Long-Term Care, Special Committee on Aging, U.S. Senate, has reported that the majority of nursing homes fail to meet standards of acceptability (34).

There is repeated documentation to support the argument that persons with varying medical conditions, with or without mechanical ventilation, can be transitioned into home care settings either at a cost equal to that in a

hospital or nursing home or, more often, at a substantial savings depending on the status of the caregiver. For instance, 102 Medicaid patients received home care services after leaving an Ohio hospital. This saved 60 per cent over the cost of care in nursing homes (35). To become more specific, a 63 year-old woman, receiving around the clock mechanical ventilation for respiratory failure due to severe bronchiectasis and pneumonia, generated monthly hospitalization charges of \$20,000. In contrast, \$10,000-\$12,000 paid for her home care, including rental of ventilator, oxygen equipment and private duty nursing fees (36).

There is even a more dramatic savings when the family plays a role in the home care. "There was no statistically significant difference in mortality between patients cared for by registered nurses around the clock as compared to care by family or nurse's aides." (33) Other savings can be effected when there are good community support services, and when equipment is purchased rather than leased. For example, a 50 year-old asbestos worker with asbestoses required chronic mechanical ventilation 10 to 24 hours daily for three years in a hospital. Later he was discharged home and was ventilated only during sleep. His hospital bills were approximately \$15,000 per month. At home, monthly expenses were about \$350 after an Emerson ventilator was purchased for \$3,500 (37). Although purchase of equipment can reduce costs, it is leased as a rule. A rather common complaint is that maintenance is more readily available for rental equipment than for machines which are purchased, a finding supported by Splaingard (33).

Satisfactory transitions to home or congregate living, have been accomplished when (1) the elderly ventilator-dependent person was as actively involved as possible in the planning process, (2) the family and/or friends had a high degree of commitment, (3) government and community support were identified and mobilized, (4) caregivers were well-trained and dedicated to the idea of mechanical ventilation and the alternative living concept. The elderly person must receive all information given to the family and/or alternative caregivers, and be involved in the training sessions. The person should receive rehabilitation in the sense of learning to do as much for himself/herself, physically and organizationally.

A respiratory therapist, whose job it is to transition persons from acute-care facilities to alternative living arrangement, estimated that the elderly constitute about five per cent of her patients. About one third were placed in long-term care facilities, and two-thirds were cared for in private homes. Failures occur when the family is not truly committed, but accedes to the wishes of the elderly, persons out of a sense of guilt, or when the elderly has no desire to live with the technology that sustains them.

Families exposed to the highly skilled nursing and life-sustaining technology in a hospital setting are often overwhelmed and too discouraged to consider the possibility that they could play a successful role in transitioning a loved one to a home situation. However, the task is not impossible. Even older children have been known to help a younger sibling to be suctioned. This success is based on their instruction in good and bad technique. Families respond much better when they know there is some

community support: when the discharging hospital stands ready to provide on-going and emergency service; when there are reliable companies that lease and maintain equipment; when there are registries for nurses, attendants and/or health aides; and when there are public monies to support final alternatives to institutional life.

With time, families find many unexpected benefits from their home care experience. In addition to that of settling into the more normal relationships, family members are relieved of the stresses and economic burdens of the routine trips to the hospital. Eventually, their increased sophistication and skills result in a great sense of accomplishment.

Good caregivers are aware that, whenever possible, the ventilator-dependent person must direct the care. In the home setting, the caregivers are prepared to become part of the family; responsibilities and roles are explicitly defined. Otherwise a great conflict occurs when the natural environment of the family is disturbed.

It is important that caregivers have good hands-on training to carry out such duties as suctioning the airway, replacement of the tracheostomy tube, chest percussion and postural drainage, etc. They need to have communication by phone, or in person, with medical personnel who will answer any questions they have so as to relieve their anxiety and carry out a good program of care. Otherwise, caregivers become fearful of life-supportive care, avoid this kind of work, or respond inappropriately when they get involved.

All caregivers involved also need access to the best current information dealing with alternative options to institutional living and with coping strategies. They need to be aware that others who have been mechanically-ventilated have achieved independent life-styles, as shown in the following illustration of a ventilator-dependent person who lived his last days at home:

R.D.G. Physical therapist, computer programmer, author, and director of medical-educational films. He was disabled by amyotrophic lateral sclerosis in 1963. He was married and the father of two grown children. Dependent upon a ventilator full-time, he lived at home with the assistance of his family and an attendant until he died in 1980. "There is hope of survival from ALS and there is a great deal which the disabled individual and his family must do to survive."

Another alternative to institutional living, and one whose benefits parallel home care, is congregate housing. The goal is to provide the relative independence of a private apartment rather than the controlled environment of a bed in a hospital or nursing home. Congregate housing can be designed to provide both personal and medical support services which will permit residents who are disabled or elderly to function on an equal basis with those who are able-bodied. In France, such group living arrangements are well-established for ventilator-dependent adults. These options enhance independence and save money because of a government-authorized category of non-professional care attendant. (27)

Just as great recognition needs to be given to transitioning persons from institutions to home care or congregate housing, there needs to be a great

awareness of the value of technical aids to the success of establishing and maintaining higher quality life-styles. Transferring some dependence upon caregiver to a independence with a technical aid makes the user responsible for its successful application. Proper utilization of technical aids enable elderly individuals to function who otherwise cannot carry out certain activities in their environment because of a physical condition and/or lack of energy. Such aids may include battery-powered wheelchairs which can accommodate respiratory equipment; environmental systems for controlling electrical appliances (bed, ventilator, telephone); and electric page-turners. For those persons who can and want to work or volunteer, adapted personal computer systems can be employed.

In our country today, there are persons of all ages who are ventilator-dependent and who want to go home. However they are forced to live out their lives in hospitals and nursing homes, because it is the policy of private and public reimbursement payment agencies, including Social Security, not to allow funds for alternatives. Sometimes a family will temporarily assume the cost of home care at great economic hardship. Eventually, they may have to terminate a good thing, with the government again paying the exorbitant cost of institutional "living."

Insurance companies also have a policy of paying for only highly skilled nursing. Yet, not all ventilator-dependent patients at home need this costly care. "Full-time care by a registered nurse was required only for one-quarter of the patients and averaged between \$15,000 and \$16,000 per month. Savings were very substantial when patients were cared for by families or

friends, or even part-time by nursing personnel" (33). It is hoped that insurance companies will soon review their policies and allow, whenever possible, reduced wages for personal care attendants and home-health aides. The money will then last longer, postponing the family's reliance on government agencies. The insurance companies can keep their own money invested for a longer period of time; insurance premiums will be less costly.

Transition for ventilator-dependent persons into non-institutional living is likely to influence in a positive way the quality of life for their remaining years and delay the time of death. The final decision as to whether or not to do this should ultimately be that of the person involved. The decision should not be made when the person is particularly ill or depressed. The decision should be made based on reliable information to alleviate unwarranted fears. The involved person should be aware that the overwhelming majority of those who have been appropriately ventilated are grateful for the technological intervention even though it is a small placement for the loss of their former vitality. It is recognized that "involuntary relocation appears to have a greater negative impact on the elderly than on any other age group." (42).

Too often it is other people who decide: the insurers who develop policies of payment, government officials who do or do not support the creation of community services, health caregivers who are influenced by the method of payment or lack of it and by their own institutional practices, physicians and other health care personnel who are unaware that there are successful

alternatives to institutional care, and families and friends who lack confidence in their ability to meet the challenge of home care.

Within the past ten years there has been an ever-growing acceptance of hospice philosophy and an increase in the number of programs. The candidate for hospice care is normally expected to die within six months, and the focus shifts from treating the disease to easing a patient's physical and mental distress.⁽⁴⁰⁾ The hospice alternative is overwhelmingly appreciated by the patient, family, and other caregivers, easing their physical and economic burdens as well as psychological oppressions of guilt, fear, and anger⁽⁴¹⁾. Medicare now offers a comprehensive hospice benefit to eligible patients cared for by hospices that meet its standards. There are about 170 hospices that have received Medicare certification,⁽⁴²⁾ However, the number of hospice programs, which include both home-care and inpatient services, is over 1,300; and the National Hospice Organization estimates that there could be as many as 6,800 in the next ten years.⁽⁴⁰⁾

As good as a hospice program is in meeting the needs of the dying, certain aspects, such as a revulsion against high-tech medicine, raise further questions: will hospice care be denied to the elderly who are already on ventilators or who are good candidates for mechanical ventilation, which will increase their comfort as it prolongs their lives? As Indihar has already stated, the ventilator-dependent elderly are virtually unweanable.

In 1983, Buckingham found that there were no hospices specifically designed to care for the terminally-ill geriatric patient (41). Others

report that more who turn to hospice care are suffering from pulmonary diseases (40). So the issue of whether or not to admit to the hospice the ventilator-dependent elderly will be increasingly evident and be added to a list of other issues crying for public debate.

Most hospice programs are home-based and offer evidence of the substantial savings in cost similar to those home-based programs set up for ventilator-dependent persons who are chronically-ill and disabled. A study published last year in the Journal of Risk and Insurance reported that the average cost over six months for a patient in a home-care hospice was \$1,319, compared with \$8,559 in a municipal hospital (40).

The families of those who are terminally-ill, not in a hospice program, and unable to afford continuous care in a hospital or long-term care facility, have to make extreme sacrifices and drastic changes in their own life style. Such indignities must also be assumed by the families of the critically-ill, and the disabled. A recent TV documentary (Frontline, PBS) presented real-life situations in which couples had to spend-down their incomes, sell their homes, and deplete their savings in order to receive public assistance. We are a society in which the elderly are left to take care of the elderly.

Conclusion

There is little direct information published or otherwise available on the subject of the elderly ventilator-dependent person. For this discussion, the authors attempted to look at the experiences of persons on ventilators in

a wide range of age groups; and the experiences of the elderly who were critically-, chronically-, and terminally-ill who had respiratory disorders. Using informal interviewing, the author uncovered the issues and obtained ideas for resolving them from those involved, i.e. elderly on ventilators, families, and caregivers.

It was noteworthy that little information is available regarding prolonged ventilation and critical illness. Most critically-ill persons either became terminally ill and die. A few became chronically ill, and these are the ones who are candidates for prolonged mechanical ventilation.

This discussion has identified such issues as (1) the lack of a positive concern for the right to a life of choice; (2) the lack of understanding about alternative lifestyles, feelings, and values; (3) the practice of decision-makers to be almost totally influenced by the regulations of the organizations for which they work or those of the reimbursement agencies; (4) the failure of nursing homes to provide standards of acceptability; (5) the lack of support by reimbursement agencies to families when they play a role in home care; and, (6) the policy of insurance companies to pay for only high skilled nursing.

The issues that have surfaced come from the experiences of those involved with the care of the elderly ventilator-dependent, i.e. ventilator-dependent persons, family, caregivers. One conclusion that all parties have come to is that there is a need for a public forum for the purpose of establishing national policy to resolve these issues. A concentrated effort to identify, mobilize, and coordinate resources can ultimately enrich our society and save monies.

4) Another Perspective

In order to put the above report into perspective, other invited commentary was sought.

The following opinion was offered by Daniel M. Kenney, Kenney & Associates, Inc.; Former Executive, Health Insurance Association of America:

"The ventilator dependent patient and the costs associated with their treatment should be of critical concern not to just the public sector, but the private sector as well. The lack of understanding of the problem and the means to assist the patient appear to be the biggest problems. Most insurance executives I know, are totally unaware of this patient population, let alone how to treat them. The fact that many doctors and hospitals have never had any exposure to this type of patient magnifies the problem even more."

"Consider the psychological impact on the patient and family members when expressing their concerns about the problem. No one knows how to treat the patient in order to assist them in getting back into the main stream of life, so they stay hospital confined. When the private insurance funds have been exhausted, the public sector is looked to for financial assistance. Many times the public sector financing forces the family to go bankrupt or become indigent before assistance is granted. More concern is expressed with who's going to pay the bill versus how we assist the patient. This begs the question: Is this the way to deal with the problem? I think most would agree that it is not."

"....The key to making it happen, however, is to get the private and public sectors to make changes in their policies to allow this alternative treatment to be compensated similarly to in-patient hospital treatment."

The following opinion was offered by Lawrence C. Morris, Senior Vice-President, Health Benefits Management, Blue Cross & Blue Shield Association:

"In general, I think that there are reasons to be optimistic that the problem inherent in the kind of care you are discussing (prolonged mechanical ventilation) are becoming more amenable to solution."

"First, the issue of propriety of treatment is receiving far more attention than it has historically. these questions are now increasingly being brought into the open, and there is reason to think that with widespread use of preadmission review, concurrent review, and other such mechanisms they will continue to be examined."

".....With the increasing focus upon cost effectiveness, I again see reason for optimism. "Managed Care" is growing rapidly, and represents a conscious effort to stretch health care dollars without adverse outcomes. As these mechanisms are complemented with increasing coverage for high technology home health services, individual benefits management (defined as the acceptance of the costs of extra-contractual services when cost-effective), support for a wider range of treatment alternatives seems to be growing."

5) A Final Commentary about the Psychological Effects on Caregivers and Family and the Impact on Dying (Goldberg)

Some elderly ventilator-dependent patients are not candidates for home care, and, because of medical or social conditions, require prolonged institutionalization. The acute care hospital may be appropriate for the initial care and acute stabilization of the ventilator-assisted patient, but a different medical model is required for prolonged care, and acute care professionals do not always understand this model. The patient has needs for early intervention by experts in psychology and rehabilitation, which are impossible and/or difficult to arrange in an institution with an acute care orientation. This lack of attention leads to secondary psycho-social maladaptation, partly due to a dehumanizing environment, and partly due to an inadequate ability to cope with such stress. Without a rehabilitative focus, the elderly person is not prepared for survival for any kind of satisfying life-style. (Alba)

Similarly, the family and caregivers need initial and long-term psychological and economic support and counselling that may not be available. This results in abnormal family adjustments and subsequent social and economic disorders

in the family. With prolonged hospitalization of the ventilator-assisted person, the caregivers in the acute care institution become frustrated by unresolved long-term issues that they are not prepared to expect, trained to handle, or willing to deal with. This results in anger, frustration, reduced satisfaction at work, and a lower quality of care. It leads to conflict with the patient and the family and a discontent that is the breeding ground for medical liability.

Other major concerns are the affect of mechanical ventilation on the cause, timing, and quality of death. If the patient has acute respiratory failure and ventilation is withheld or prematurely withdrawn, the patient will die at some point in time. There is no guarantee how rapidly this will occur nor that this will be a smooth process. As with the decision to use the ventilator, prognostic uncertainty remains the major obstacle. All that is certain is that "life is a condition with a 100% mortality" (G. Spencer).

The major concern for these in an acute situation is one where an elderly person may be at home or in a nursing home and suddenly deteriorate (B. Make). There may be a sudden arrest, no do not resuscitate order, and the elderly person is brought to the hospital by emergency medical technicians who do. Under these circumstances, the process and timing of death is unnaturally altered. Such a scenario could be avoided if decisions are made prior to the acute event. This should include the elderly person, if mentally competent; if not, the family and physicians should make this prior determination (B. Make).

Another major concern is the effect that current reimbursement policies (DRG's) will have on the inappropriate continuing or discontinuing of mechanical ventilation and its effect on dying. Either DRG's will force premature withdrawal, with resulting death or medical instability, or transfer to a less-costly site of care, where the ventilation may be prolonged for inappropriate reasons (professional incompetence, economic factors). Although most contributors to the OTA Survey (Task #3) did not expect an increase in the number of elderly patients who require prolonged mechanical ventilation, this anticipated effect of reimbursement policy has already been observed (Giovannoni).

In the chronic situation, prolonged mechanical ventilation is not an emergent, but an elective, decision which usually made by the patient, family, and physician (See OTA Task #5). If this prolongs life, it does so at the desire of those involved to whom this decision will impact and who have decided that it is worth the effort. This desire is crucial for any successful outcome. To most contributors of the OTA Survey, this elective use of prolonged mechanical ventilation to enhance the lives of (younger) persons with chronic illness is the most frequent indication and has a favorable prognosis. The incidence of prolonged mechanical ventilation for this patient group is small and is anticipated to remain so. (See OTA Survey Task #3)

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Contract 533-4935.0

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TASK 4

APPENDIX

Outcome of respiratory intensive care for the elderly

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We followed 1018 patients admitted consecutively to multidisciplinary respiratory ICU (RICU), with special attention to patients aged 75 yr and over. The elderly had a higher RICU (11/49) and in-hospital (21/30) mortality than younger patients. The 28 survivors of hospitalization had a lower acute physiology score (APS) than nonsurvivors on admission (16.1 ± 7.8 vs. 1.8 ± 8.9 , respectively), indicating less severe illness. The quality of long-term survival (12 to 24 months) was assessed using an open-ended questionnaire. Eighteen hospital survivors were alive at the time of follow-up and the quality of life was deemed satisfactory by 10 of 13 patients who were living independently. Only two of 18 survivors had been transferred to nursing home care, and two were in acute care hospitals.

We conclude most elderly patients discharged from the RICU consider their lifestyle satisfactory and are not a large drain on community health care resources. Further studies of the screening process which determines RICU admission are necessary, because unimodal criteria such as age and APS after admission were not of prognostic value.

The elderly are increasing in both absolute and proportional numbers, and in the future they will use a greater proportion of health care resources. In respiratory ICUs (RICUs), costs are high, and data on the prognosis of elderly patients with respiratory failure may help in developing strategies for resource utilization in critical care areas. A number of studies¹⁻⁴ have described outcome of intensive care; however, few have specifically concentrated on elderly patients.

This study reviews short-term and long-term outcomes of RICU patients, particularly those patients 75 yr and older requiring ventilatory support.

SUBJECTS AND METHODS

Hospital and RICU

St. Michael's Hospital is a 701-bed, tertiary care facility affiliated with the University of Toronto. It is located in Toronto, a city of 2,500,000 people. All surgical and medical subspecialties are represented in this facility.

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The RICU is a 14-bed multidisciplinary unit, supervised and staffed by members of the department of anesthesia. The unit's nursing staff provides one nurse per patient. Indication for admission is the requirement for mechanical ventilation and/or invasive hemodynamic monitoring. With all admissions the primary physician (medical or surgical) decides that intensive care is appropriate, and requests an RICU consult. If the RICU staff agrees that there is a potentially reversible cause of cardiorespiratory failure, the patient is admitted. Neurosurgical patients are cared for in a separate ICU and were not part of this study group. All other patients requiring ventilatory support are cared for in the RICU.

Study Design

We studied all patients admitted to the RICU between April 1, 1982, and March 31, 1983. For each patient the following information was documented: primary diagnoses noted by the RICU staff at the time of admission according to the ICD-9 classification;⁵ age, sex, the duration of ventilatory support, length of RICU stay, total length of hospitalization, and survival of both RICU and hospitalization.

The charts of elderly patients (75 yr or older) were reviewed, and an acute physiology score (APS)⁶ was calculated for those patients remaining in the RICU longer than 12 h, using data from the first 24 h of their RICU stay. APS is a physiologically based classification system⁶ used to assess severity of illness in critically ill patients.

The elderly patients were broadly classified into five subgroups, as follows: group 1—postoperative cardiac surgery (elective and emergency); group 2—postoperative noncardiac elective surgery, including general and major vascular surgery; group 3—postoperative emergency noncardiac surgery; group 4—postoperative complications admitted from the wards, emergency department, or transferred from other facilities; and group 5—nonoperative admissions (medical and surgical).

The survivors of hospitalization in the elderly patient group were contacted by telephone by one of the authors (R.M.) 12 to 24 months after discharge. An open-ended questionnaire was used to ascertain the following information: present living situation; functioning activity status at the time of follow-up; number of hospital-

izations since discharge; frequency of physician visits; attitudes towards present quality of life; and willingness, under the same circumstances, to undergo similar therapy again.

Finally, we documented all non-neurosurgical hospital deaths during this 1-yr period, in order to compare the number of hospital deaths to the number of RICU deaths in similar patients aged 75 yr and over.

Statistical Analysis

Data were expressed as mean $\pm$ 1 SD. Differences between groups were evaluated using an unpaired *t*-test, and the Chi-square test was used to compare proportions between RICU survival and nonsurvival groups. A *p*-value under .05 was considered significant.

RESULTS

During this 12-month study period 84% of the 1018 patients were postoperative admissions. The nonoperative RICU admissions (16%) were transfers from the wards, emergency department, or other hospitals. The largest single group (63%) was composed of postoperative cardiac surgical patients, who had an overall hospital mortality rate of 5.4%, including emergency and elective cases. The RICU mortality rate was 11.2%, and a further 6.7% died after RICU discharge.

The hospital mortality rate was significantly (*p* < .005) higher in elderly patients than in the rest of the patient population. There was, however, no difference in hospital survival between patients aged 75 yr and older and those aged 65 to 74 yr (Table 1). Both the RICU and hospital average length of stays were significantly longer for these two groups than for younger (under 65) patients.

Figures 1 and 2 show the RICU average length of stay (ALOS) and duration of ventilation for the elderly population compared to the rest of the RICU patients.

Elderly Patient Population

Forty-nine patients 75 yr of age or over accounted for 54 RICU admissions. The majority (83%) of admissions in this group were noncardiac surgical patients; by comparison, only 30% (331/964) of younger patients were admitted after noncardiac surgery (*p* < .005).

Table 2 shows the distribution of elderly admissions by source of referral; there were no significant differences in survival between these groups. Only one of nine postoperative patients admitted to the RICU from the wards (group 4) survived hospitalization. Postoperative complications prompting RICU admission in this group were: renal failure (three cases), pulmonary edema (two cases), cardiopulmonary arrest (three cases), and aspiration pneumonia (one case). The cause of death in the entire group of elderly patients was frequently multiorgan failure characterized by cardio-respiratory arrest (nine cases), sepsis (three cases), renal failure (four cases), and pulmonary edema (three cases).

The mean APS in this elderly population was 18.8 ± 8.6 for the first 24 h after admission. Survivors had a significantly lower APS (16.1 ± 7.8) than nonsurvivors (21.8 ± 8.9). None of the five patients who received hemodialysis in the RICU survived hospitalization.

RICU Utilization

There were 1018 non-neurosurgical admissions for whom data collection was complete; their RICU ALOS was 4.3 ± 8.1 days, yielding a total of 4377 RICU bed days. Patients 75 yr and older accounted for 437 (10%) RICU bed days but only 54 (approximately 5%) RICU admissions.

During the study period there were 188 in-hospital deaths of non-neurosurgical patients aged 75 yr or older who could have been referred for RICU admission. Twenty elderly patients died in hospital, having been admitted to the RICU. Thus, "in-hospital" mortality of

TABLE 1. Comparison of data from specific age groups

Age (yr)	Total Admissions	RICU Survivors	Hospital Survivors	Average Length of Stay	
				RICU (days)	Hospital (days)
Unknown	5	2	2	5.6 ± 9.7	19 ± 11
0-19	4	4	3	1.0 ± 0	15.8 ± 14.4
20-34	50	47	44	6.3 ± 10.5	27.6 ± 35.4
35-44	102	95	93	3.0 ± 5.5	17.7 ± 20.7
45-54	213	203	195	2.6 ± 4.9	15.4 ± 19.2
55-64	377	342	324	3.5 ± 5.6	19.8 ± 23.6
65-74	213	170	146	6.8 ± 11.7	28.4 ± 34.8
≥ 75	54	41	29	7 ± 13.1	32.3 ± 45.6
	1018	904	836	$4.3 \pm 8.1^*$	$21.5 \pm 27.9^*$

* Overall mean.

patients who had been admitted to RICU represented 10.6% of the 188 comparable non-neurosurgical deaths in this age group.

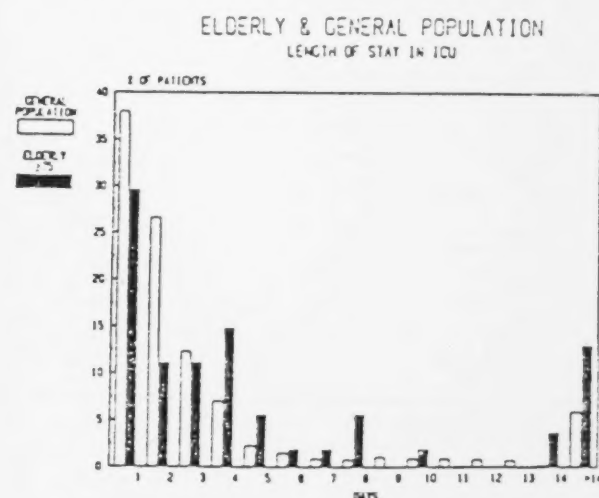


FIG. 1. Length of RICU stay for the elderly compared to that for the entire population.

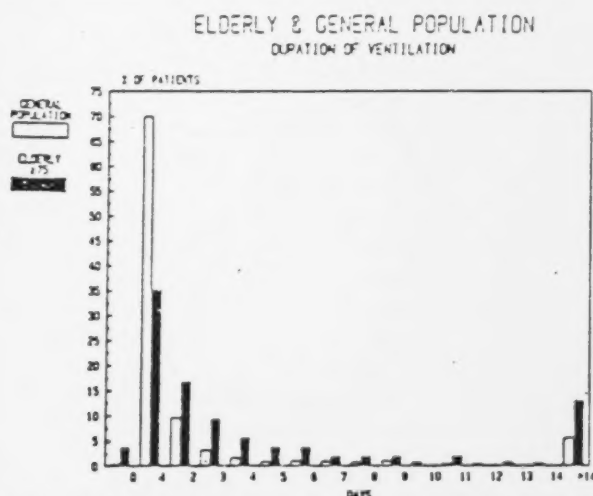


FIG. 2. Duration of ventilation of the elderly compared to that of the entire population.

Long-Term Follow-Up

Table 3 summarizes the 12- to 24-month follow-up results. All surviving patients were interviewed. Six of the 14 long-term survivors were from groups 3, 4, and 5 and, therefore, not elective surgical admissions. Their admission diagnoses included perforated bowel, pulmonary hemorrhage, leaking abdominal aortic aneurysm (two cases), post-trauma, and cardiac arrest with pacemaker failure.

Of the 14 patients living in the community without assistance, ten were living alone or with spouses. One patient had been house-bound for 6 months before follow-up, and three were dependent on children to varying degrees. No patient required community assistance at home. Six of these 14 patients rated their activity level as higher or the same as their premorbid state. Ten of 13 said they would undergo similar treatment again, and 11 of 13 patients believed their quality of life was acceptable and worthwhile. Only two of these 14 patients had been readmitted to the hospital since discharge.

The two patients in acute care hospitals at the time of follow-up had complicated postdischarge courses and were not expected to survive the present illness.

DISCUSSION

A preliminary study⁷ in our unit showed that RICU survivors were functioning independently in society 8 to 10 months after discharge. The present study specifically evaluated outcome in a larger group of elderly RICU survivors.

Our findings agree with other studies^{1,3,8} showing the elderly to have a higher short-term as well as long-term mortality rate compared to younger patients. However, it is difficult to compare statistics from different studies because of differences in patient populations. For example, in the study by Campion et al.¹ of medical intensive care, the cumulative mortality for patients over 75 yr of age was 44% at 1 yr—primarily related to myocardial infarction; however, 71% of these patients were admitted for monitoring only, and only 31% of these required even one intervention. In contrast, all of

TABLE 2. Elderly subgroups

Admission Characteristics	Group 1	Group 2	Group 3	Group 4	Group 5
No. of patients	7	11	11	9	14
Age (yr)	76.9 ± 2.8	78.6 ± 4.4	80.5 ± 4.7	78.7 ± 4.4	78.5 ± 4.5
ICU average length of stay	3.9 ± 1.6	3.0 ± 2.8	14.4 ± 25.9	5.4 ± 4.1	7.7 ± 9.5
Duration of ventilation (days)	2 ± 1.2	2.3 ± 2.3	13.8 ± 25.9	4.6 ± 2.5	6.2 ± 8.7
APS	17.3 ± 6.6	13.6 ± 4.6	17.6 ± 8.2	20.9 ± 6	22.9 ± 11.3
ICU survivors	7	11	8	4	11
ICU readmissions	0	0	0	3	2
Hospital survivors	7	8	7	1*	6

* Patient initially admitted in group 3.

TABLE 3. Life-styles of 18 RICU survivors 12 to 24 months after hospital discharge

	Living at Home with Community Services	Living in Nursing Home	In-Patients in an Acute Care Hospital
Group 1 (n = 7)	5		2
Group 2 (n = 11)	3	1	
Group 3 (n = 11)	4	1	
Group 4 (n = 9)	1*		
Group 5 (n = 14)	2	2	2
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* Patient previously admitted in group 3, therefore counted twice.

our RICU patients required interventions such as arterial cannulation, ventilatory support, and/or invasive hemodynamic monitoring of cardiorespiratory variables.

Knaus et al.⁶ emphasize that the need and potential benefit of intensive care are determined by the active disease process, the severity of illness, the patient's premorbid health status before RICU admission, the efficacy of available therapy, and the patient's age. To clarify the limits of our therapeutic capabilities in elderly RICU patients, investigators need a common currency to describe various disease processes, health status, and severity of illness. The APACHE system⁶ shows that acute physiologic abnormalities (as measured by the APS) have the same effect on mortality in a variety of tertiary care centers. Our mean APS for elderly hospital survivors was lower than for elderly nonsurvivors (16.1 ± 7.8 vs. 21.8 ± 8.9 , respectively). Our overall APS (18.8 ± 8.6) and in-hospital mortality rate for elderly patients suggest a higher mortality rate adjusted for severity of illness than for comparable groups of younger patients.⁸ Thus, elderly patients appear to have a greater risk of dying for any severity of disease process (APS), presumably related to a decrease in physiologic reserve with aging. A revised version of the APACHE system accommodates age as an independent risk factor.

In a large survey⁹ of ICU utilization, the overall age distribution was not dissimilar from that in the general hospital population, except for slightly fewer admissions above age 70 yr. This trend was also noted by Campion et al.¹ and suggests that physicians may be less aggressive when treating acute problems in elderly patients. In our study the majority of elderly patients dying of non-neurosurgical causes were not admitted for RICU care. This suggests that an active screening process by primary physicians already exists in our hospital.

Our study found that most elderly RICU survivors were independent (Table 3) and considered their quality

of life satisfactory, similar to younger patients.⁷ Surprisingly, Table 2 shows that the elderly survivors were not all in the low-risk elective cardiac and noncardiac surgical groups admitted to the RICU (groups 1 and 2). In fact, 13 of 28 elderly hospital survivors were in the high-risk groups: emergency noncardiac surgical admissions (group 3), postoperative complications (group 4), and nonoperative admissions (group 5).

Guidelines to identify patients who clearly do not benefit from RICU care are needed. Draper et al.¹⁰ suggest that in multiorgan failure, survival becomes unprecedented when three or more organ system failures persist for over 48 h. In our elderly group no dialyzed patients with respiratory failure and renal failure survived. However, this type of criterion must be prospectively evaluated in a large group (we had only five patients), and continually re-evaluated as improved therapeutic interventions become available.

Our experience suggests that an individualized approach to decision-making by experienced clinicians can result in the utilization of an RICU facility for many patients aged 75 yr and over who will return to a worthwhile lifestyle. Strategies for resource allocation cannot be based solely on such unimodal criteria as age and APS, although these factors can be used by clinicians to evaluate outcome and improve prognostic capabilities.

Results of RICU care are clearly dependent on the screening process determining patient admission. Most studies^{1-3,8,11,12} of ICU costs and effectiveness have focused on patient status after admission. Future studies must consider factors that prompt referral to the RICU.

The most costly ICU admissions are those patients who have unexpected outcomes.¹¹ In our study, elderly readmissions to the RICU (group 4) had a very poor outcome (Table 2). Whether unexpected complications could have been prevented remains speculative.

We conclude that most elderly survivors of respiratory intensive care consider their lifestyle worthwhile and are not a large drain on community health care resources. Rationing strategies for the RICU need to consider the screening process, including the patient's chronic health status as well as postadmission data.

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TASK 4
APPENDIX

Outcome of respiratory intensive care for the elderly

RICHARD F. McLEAN, MD; JULIE D. McINTOSH, CCHRA(C); GEORGE Y. KUNG, BScE, CCHRA(C);
DAVID M. W. LEUNG, CCHRA(A); ROBERT J. BYRICK, MD, FRCP(C)

We followed 1018 patients admitted consecutively to multidisciplinary respiratory ICU (RICU), with special attention to patients aged 75 yr and over. The elderly had a higher RICU (11/49) and in-hospital (21/49) mortality than younger patients. The 28 survivors of hospitalization had a lower acute physiology score (APS) than nonsurvivors on admission (16.1 ± 7.8 vs. 1.8 ± 8.9 , respectively), indicating less severe illness. The quality of long-term survival (12 to 24 months) was assessed using an open-ended questionnaire. Eighteen hospital survivors were alive at the time of follow-up and the quality of life was deemed satisfactory by 10 of 13 patients who were living independently. Only two of 18 survivors had been transferred to nursing home care, and two were in acute care hospitals.

We conclude most elderly patients discharged from the RICU consider their lifestyle satisfactory and are not a large drain on community health care resources. Further studies of the screening process which determines RICU admission are necessary, because unimodal criteria such as age and APS after admission were not of prognostic value.

The elderly are increasing in both absolute and proportional numbers, and in the future they will use a greater proportion of health care resources. In respiratory ICUs (RICUs), costs are high, and data on the prognosis of elderly patients with respiratory failure may help in developing strategies for resource utilization in critical care areas. A number of studies¹⁻⁴ have described outcome of intensive care; however, few have specifically concentrated on elderly patients.

This study reviews short-term and long-term outcomes of RICU patients, particularly those patients 75 yr and older requiring ventilatory support.

SUBJECTS AND METHODS

Hospital and RICU

St. Michael's Hospital is a 701-bed, tertiary care facility affiliated with the University of Toronto. It is located in Toronto, a city of 2,500,000 people. All surgical and medical subspecialties are represented in this facility.

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The RICU is a 14-bed multidisciplinary unit, supervised and staffed by members of the department of anesthesia. The unit's nursing staff provides one nurse per patient. Indication for admission is the requirement for mechanical ventilation and/or invasive hemodynamic monitoring. With all admissions the primary physician (medical or surgical) decides that intensive care is appropriate, and requests an RICU consult. If the RICU staff agrees that there is a potentially reversible cause of cardiorespiratory failure, the patient is admitted. Neurosurgical patients are cared for in a separate ICU and were not part of this study group. All other patients requiring ventilatory support are cared for in the RICU.

Study Design

We studied all patients admitted to the RICU between April 1, 1982, and March 31, 1983. For each patient the following information was documented: primary diagnoses noted by the RICU staff at the time of admission according to the ICD-9 classification;⁵ age, sex, the duration of ventilatory support, length of RICU stay, total length of hospitalization, and survival of both RICU and hospitalization.

The charts of elderly patients (75 yr or older) were reviewed, and an acute physiology score (APS)⁶ was calculated for those patients remaining in the RICU longer than 12 h, using data from the first 24 h of their RICU stay. APS is a physiologically based classification system⁶ used to assess severity of illness in critically ill patients.

The elderly patients were broadly classified into five subgroups, as follows: group 1—postoperative cardiac surgery (elective and emergency); group 2—postoperative noncardiac elective surgery, including general and major vascular surgery; group 3—postoperative emergency noncardiac surgery; group 4—postoperative complications admitted from the wards, emergency department, or transferred from other facilities; and group 5—nonoperative admissions (medical and surgical).

The survivors of hospitalization in the elderly patient group were contacted by telephone by one of the authors (R.M.) 12 to 24 months after discharge. An open-ended questionnaire was used to ascertain the following information: present living situation; functioning activity status at the time of follow-up; number of hospital-

izations since discharge; frequency of physician visits; attitudes towards present quality of life; and willingness, under the same circumstances, to undergo similar therapy again.

Finally, we documented all non-neurosurgical hospital deaths during this 1-yr period, in order to compare the number of hospital deaths to the number of RICU deaths in similar patients aged 75 yr and over.

Statistical Analysis

Data were expressed as mean $\pm$ 1 SD. Differences between groups were evaluated using an unpaired *t*-test, and the Chi-square test was used to compare proportions between RICU survival and nonsurvival groups. A *p*-value under .05 was considered significant.

RESULTS

During this 12-month study period 84% of the 1018 patients were postoperative admissions. The nonoperative RICU admissions (16%) were transfers from the wards, emergency department, or other hospitals. The largest single group (63%) was composed of postoperative cardiac surgical patients, who had an overall hospital mortality rate of 5.4%, including emergency and elective cases. The RICU mortality rate was 11.2%, and a further 6.7% died after RICU discharge.

The hospital mortality rate was significantly ($p < .005$) higher in elderly patients than in the rest of the patient population. There was, however, no difference in hospital survival between patients aged 75 yr and older and those aged 65 to 74 yr (Table 1). Both the RICU and hospital average length of stays were significantly longer for these two groups than for younger (under 65) patients.

Figures 1 and 2 show the RICU average length of stay (ALOS) and duration of ventilation for the elderly population compared to the rest of the RICU patients.

Elderly Patient Population

Forty-nine patients 75 yr of age or over accounted for 54 RICU admissions. The majority (83%) of admissions in this group were noncardiac surgical patients; by comparison, only 30% (331/964) of younger patients were admitted after noncardiac surgery ($p < .005$).

Table 2 shows the distribution of elderly admissions by source of referral; there were no significant differences in survival between these groups. Only one of nine postoperative patients admitted to the RICU from the wards (group 4) survived hospitalization. Postoperative complications prompting RICU admission in this group were: renal failure (three cases), pulmonary edema (two cases), cardiopulmonary arrest (three cases), and aspiration pneumonia (one case). The cause of death in the entire group of elderly patients was frequently multiorgan failure characterized by cardiorespiratory arrest (nine cases), sepsis (three cases), renal failure (four cases), and pulmonary edema (three cases).

The mean APS in this elderly population was 18.8 ± 8.6 for the first 24 h after admission. Survivors had a significantly lower APS (16.1 ± 7.8) than nonsurvivors (21.8 ± 8.9). None of the five patients who received hemodialysis in the RICU survived hospitalization.

RICU Utilization

There were 1018 non-neurosurgical admissions for whom data collection was complete; their RICU ALOS was 4.3 ± 8.1 days, yielding a total of 4377 RICU bed days. Patients 75 yr and older accounted for 437 (10%) RICU bed days but only 54 (approximately 5%) RICU admissions.

During the study period there were 188 in-hospital deaths of non-neurosurgical patients aged 75 yr or older who could have been referred for RICU admission. Twenty elderly patients died in hospital, having been admitted to the RICU. Thus, "in-hospital" mortality of

TABLE 1. Comparison of data from specific age groups

Age (yr)	Total Admissions	RICU Survivors	Hospital Survivors	Average Length of Stay	
				RICU (days)	Hospital (days)
Unknown	5	2	2	5.6 ± 9.7	19 ± 11
0-19	4	4	3	1.0 ± 0	15.8 ± 14.4
20-34	50	47	44	6.3 ± 10.5	27.6 ± 35.4
35-44	102	95	93	3.0 ± 5.5	17.7 ± 20.7
45-54	213	203	195	2.6 ± 4.9	15.4 ± 19.2
55-64	377	342	324	3.5 ± 5.6	19.8 ± 23.6
65-74	213	170	146	6.8 ± 11.7	28.4 ± 34.8
≥ 75	54	41	29	7 ± 13.1	32.3 ± 45.6
	1018	904	836	$4.3 \pm 8.1^*$	$21.5 \pm 27.9^*$

* Overall mean.

patients who had been admitted to RICU represented 10.6% of the 188 comparable non-neurosurgical deaths in this age group.

ELDERLY & GENERAL POPULATION
LENGTH OF STAY IN ICU

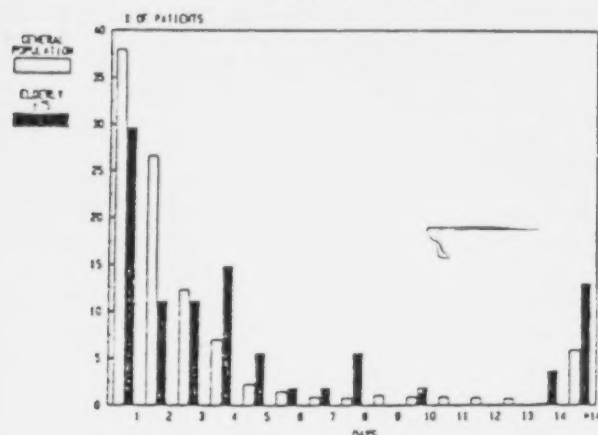


FIG. 1. Length of RICU stay for the elderly compared to that for the entire population.

ELDERLY & GENERAL POPULATION
DURATION OF VENTILATION

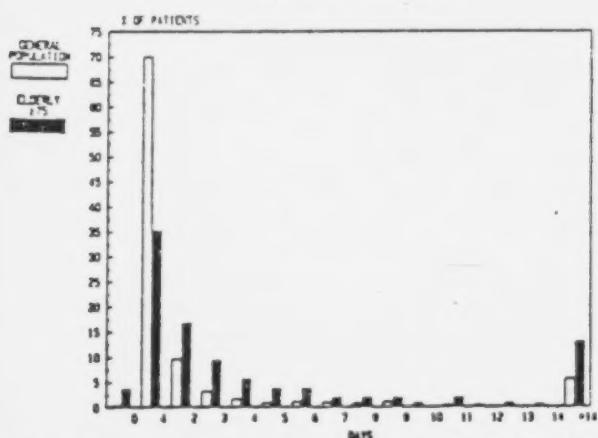


FIG. 2. Duration of ventilation of the elderly compared to that of the entire population.

Long-Term Follow-Up

Table 3 summarizes the 12- to 24-month follow-up results. All surviving patients were interviewed. Six of the 14 long-term survivors were from groups 3, 4, and 5 and, therefore, not elective surgical admissions. Their admission diagnoses included perforated bowel, pulmonary hemorrhage, leaking abdominal aortic aneurysm (two cases), post-trauma, and cardiac arrest with pacemaker failure.

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California Health Decisions

Involving Citizens in Health Care Choices

Recent dramatic headlines have focused public attention on ethical issues in health care:

Baby Fae Receives a Baboon Heart

Patient Seeks Legal Help to Force Hospital to 'Pull the Plug'

Father Goes on National Television Seeking a Liver Transplant for His Daughter

Thirty-Five Million Americans Lack Health Insurance

Federal Government Issues 'Baby Doe' Regs for the Treatment of Seriously Ill Newborns

As medical technology advances, as the amount of money available for health care is constrained and as values conflict, these and other situations are becoming more common.

Critical choices need to be made about how much should be spent on health care and where the money should go. How should we divide up our tax dollars between programs to prevent disease and those that cure or retard it? How should care be financed for the medically indigent? Most citizens have no idea of how choices are made about the allocation of health resources yet those choices have a profound effect on them.

Other questions concern choices affecting medical treatment. What kind of care is appropriate for seriously ill newborns? For terminally ill patients? Who decides when the most aggressive and sophisticated medical treatments available are not in the best interests of the patient?

Ethical, financial and legal questions in health care continue to increase at a rapid rate. What we need is a better way to answer them -- a way that involves ordinary citizens. California Health Decisions is a creative new effort to do just that. During a series of small group and town hall meetings, the citizens of Orange County will have an opportunity to identify the social values and priorities they think ought to be used as a basis for health policies and professional practices.

PROJECT TIME TABLE

California Health Decisions will hold a training conference for approximately 75 community leaders in October 1985. Following this, small groups and town hall meetings will be used to impart information and solicit public opinion. These meetings will take place in various community locations over a period of several months.

The second phase will include broad public dissemination of the issues and recommendations identified during these meetings. In the fall of 1986, a Citizens Health Care Parliament, consisting of elected community representatives, will meet for two days to formulate specific recommendations. The results of the Citizens Health Care Parliament will be published and made available to a wide audience, including health care policy makers and providers at the local state and federal levels.

California Health Decisions includes a plan for follow-up and assistance to policy makers and others who are in a position to implement the citizen recommendations generated by the project.

PROJECT ORGANIZATION

California Health Decisions is modeled after a pioneer project called Oregon Health Decisions, held throughout the state of Oregon in 1983 and 1984. Our project will take place in Orange County, but it is anticipated that other areas in California will launch similar projects. The Orange County Health Planning Council and the Center for Bioethics at St. Joseph Health System, Orange, have collaborated to develop the project. It will be conducted under the aegis of the Southern California Health Resources Center, the nonprofit, 501(c)(3) action arm of the Orange County Health Planning Council.

The Orange County Health Planning Council is the federally-designated Health Systems Agency for Orange County. Its goals are to increase public accountability of the health care system and to implement policies which will limit costs while assuring quality services and availability. In order to emphasize implementation as well as planning, it established the Southern California Health Resources Center, a nonprofit corporation, as its action arm.

The Center for Bioethics at St. Joseph Health System, Orange, offers educational programs and consultation services in bioethics to hospitals, nursing homes, professional organizations and associations, as well as professional and lay persons.

The California Health Decisions--Orange County Project will be directed by an Advisory Board which is broadly representative of community values and perspectives.

ASSUMPTIONS

1. The proper development of public policy on health decisions must include consideration of societal values and a way to identify and incorporate those values.
2. If we are to find long-term solutions to high cost medical care and inequalities in access to care, the problems should be faced and understood by the local communities.
3. An informed public, concerned health professionals and a wise, restrained government are all necessary to open, prudent discourse on health decisions.
4. Increased public awareness of the critical health decisions families must make in the coming decades calls for a special educational effort endorsed and fostered by state and community leaders.
5. The wishes and preferences of individuals, patients and families should be the central consideration in health decisions.
6. Decisions involving medical treatment and other health care choices should be made in an atmosphere of interactions between individuals/patients, families, and health care professionals. Enactment of legislation and/or government intervention in these matters should occur only as a last resort.

SOURCES OF SUPPORT

Funds to support the project are being sought from foundations, businesses, health-related organizations and the general public. Contributions are tax-deductible. All contributors will be listed in the final conference proceedings and will receive special updates throughout the course of the project.

Checks should be made payable to California Health Decisions and sent to:

California Health Decisions
c/o Southern California Health Resources Center
202 Fashion Lane, Suite 219
Tustin, California 92680

Inquiries should be addressed to Ellen B. Severoni, Project Director, at the same address. Telephone number is (714) 832-1841.

Tuesday, August 6, 1985

Dealing With Ethics of Health Care

Project Involves Public in Cost, Technology, Rights Issues

By DENNIS McLELLAN, Times Staff Writer

Taking her place behind a makeshift podium, Sister Corrine Bayley scanned the crowd of more than 200 Orange County residents jammed into the Costa Mesa City Council chambers.

"This is not just the beginning of a meeting," Bayley said, "but the beginning of a movement that I think could be for the '80s what civil rights was for the '60s."

Thus began the first public meeting of California Health Decisions—Orange County Project, an ambitious, countywide project sponsored by the Orange County Health Planning Council and the Center for Bioethics at St. Joseph Health System in Orange.

Beginning this fall, it will begin seeking public opinion—and recommendations—on the many difficult ethical issues in health care that have emerged in the wake of life-prolonging medical technology and increasingly high medical costs.

Those issues include such questions as: Is it appropriate in every case to use life-prolonging technology? Do people have the right to health care? If so, how much? What areas of health care should have priority in the allocation of tax dollars?

Modeled after a pioneer project conducted in Oregon in 1983 and 1984, California Health Decisions—Orange County Project is the first such effort to be undertaken in California.

"We are on the ground floor of a movement that can shape the future of health care," observed Bayley, director of the Center for Bioethics and vice president of St. Joseph Health System. "We have an opportunity to take part in what is becoming one of our most crucial domestic issues: health-care rights and choices."



CALIFORNIA
HEALTH
DECISIONS
ORANGE
COUNTY

First part in an occasional series.

"How the issues are decided will affect us all."

California Health Decisions—Orange County Project calls for a series of public meetings to be held throughout the county over a seven-month period.

As outlined at the Tuesday night opening meeting by project director Ellen Severoni, more than 200 small group meetings will be conducted between October of this year and February, 1986. Those will be followed by at least 12 large town hall meetings to be held between February and May.

In October, 1986, delegates who have been nominated at the meetings will meet in a Citizens Health Care Parliament. They will examine all the data collected at the meetings, debate it, refine it and prioritize it.

The result, Severoni said, will be a series of health-care recommendations that will be passed on to policy makers and health-care providers.

"Not so many years ago, a project like this one would have been unthinkable, and that's because the health-care choices and the costs we face today were also unthinkable not so many years ago," Bayley said.

In the past few decades, she said, "we have witnessed the development of amazing medical technology and sophisticated forms of treatment that are now in widespread use. If you think about it, we are really living at a time when human beings have an almost unprecedented control over life and death."

Indeed, she said, it is an age in which "we can start a failed heart; we can keep people living long beyond the time they would (previously) have died, with such



ANNE DOWIE

Ellen Severoni, left, and Sister Corrine Bayley at California Health Decisions—Orange County Project meeting in Costa Mesa.

things as coronary artery bypass surgery, organ transplants, ventilators and neonatal intensive care units.

"We have artificial hearts and artificial kidneys and research is proceeding on artificial livers, lungs, placentas, and the list goes on."

We can conceive human life outside the womb, and we can transplant an embryo from one womb into another. Research is proceeding on cloning, on extending the life span, on genetic engineering and freezing bodies for some future resurrection. . . ."

Bayley said she agrees with a philosopher who declared, "Never has so much knowledge been coupled with so little guidance for its use."

"And where," she asked the audience, "will that guidance come from?"

"We're hoping it will come from people like you—people who are interested enough to come out tonight, people who are proud of what our health-care system has done but who are aware that there are significant areas that need improvement."

Among the 228 Orange County citizens who turned out for the project's introductory meeting were doctors, nurses and other health-care professionals, representatives of city governments and at least 70 ordinary citizens—people like Gloria Davenport of Orange.

"I think it's about time for the public to be involved," said Davenport, a counselor and instructor at Rancho Santiago College in Santa Ana, who described the project as "an opportunity for the public to be awakened to the need to look at whether we can live or die with dignity."

"I have a deep concern that something be done to make the public free to make decisions without getting legal repercussions," she said. "I'm excited tonight in seeing the interest in professionals and the lay public."

Project director Severoni, a registered nurse, was equally excited at the conclusion of the meeting, which resulted in more than 60 volunteers signing up to serve as group leaders, who will be trained to facilitate the public meetings.

"I'm really pleased as punch," Severoni said. "The momentum is here, the issues are timely and the community is concerned—and that's what I think I saw tonight."

Until now, Severoni said, "The public hasn't been involved in health-care issues" because people haven't had a formal mechanism to influence how health care is delivered.

Although Orange County is currently the only area involved in California Health Decisions, Severoni said she has received commitments from health planning agencies throughout the state to replicate the Orange County Project.

As a result of the Oregon Health Decisions project, Severoni said, five other states also are now conducting projects of their own, and the Prudential Insurance Foundation has begun offering grants for "local decision-making in bioethics."

California Health Decisions, a nonprofit organization with a 37-member advisory board, recently received a \$15,000 first-year grant from Prudential. Severoni stressed, however, that the grant is only seed money for conducting the project and that other grant applications are being made. She added that more than \$4,000 in donations also has been raised from local hospitals.

Referring to the Oregon Health Decisions project, Severoni said that one consensus from that project was that everyone is entitled to an adequate level of health care.

The Oregon project's recommendations were turned over to the state Legislature, but she said the Legislature has asked that the project be reinstated: that the organizers go back to the citizens to define exactly what they mean by "adequate level of care" and how that care is going to be paid for.

Although Severoni noted that legislation may come as a result of the California Health Decisions' recommendations, she told the audience that "we as a community

can begin to make some decisions for ourselves that will not require legislation. Our hospitals are in need of some guidelines on how we expect these (ethical) decisions to be made."

Bayley, who has been working full time in the field of bioethics since 1978, gave the audience an overview of the types of medical and ethical issues Orange County residents will be discussing over the next year.

She spoke of rising health-care costs, noting that nearly \$400 billion a year is now spent on health care in this country and that individuals, who spent about \$211 on health care in 1965, spent about \$2,166 per person in 1984.

And she spoke on the issue of whether Americans have access to adequate health care.

"The answer is definitely no," said Bayley, explaining that approximately 30 to 35 million Americans—about one in eight people—have no health insurance.

insurance, it's very difficult to get care these days, especially if it is not a grave emergency. Health care is becoming more a commodity whether you like it or not."

She added that "cuts in prenatal care have led, some would say and I would agree, to an increase in infant mortality. It is ironic, I think, that we are cutting back in prenatal care, and yet when a baby is born prematurely, basically because of cutbacks in prenatal care, we spend enormous amounts of money in neonatal intensive care units caring for that child."

Bayley said the U.S. infant mortality rate is worse than in 16 other industrialized countries "and for blacks in our country it is twice as bad as it is for whites."

At the same time this is happening, she said, "we are spending about \$300 million annually for transplants: heart, liver, kidneys, pancreas and so on, and if the supply of organs increases, it is estimated that we will be spending about \$3 billion a year. I'm not saying that's bad, I'm saying we need to know what the trade-offs are."

Although "enormous amounts of money" are spent to save one person, Bayley said, "there are hundreds of children who are dying for lack of adequate food and health care in this country, but they are unidentified."

She recalled Jamie Fiske, the young daughter of a Boston hospital administrator who needed a liver transplant a few years ago. The girl's father, Bayley said, was "a very articulate, savvy man who knew public relations" and who succeeded in getting his daughter a liver transplant after taking his appeal to the media.

But at about the same time, Bayley said, there was a 6-year-old boy in Chicago whose mother was on welfare. She did not have money, was not articulate, did not have access to the media and, Bayley said, the boy did not get a liver transplant.

"It seems to me, that is not a fair way—or a good way—to be making decisions about who should have access to care," Bayley said. "We hope California Health Decisions—Orange County Project will give us a chance to be more involved in the kinds of policies and underlying principles we want to govern our health-care choices. We need to deal with it as a society."

"The decisions we face are clearly difficult decisions about who will live and who will die, decisions about who will decide who will live and who will die, decisions about whether health care is a commodity or a right, decisions about trade-offs between basic care and high-tech care, decisions about how health care should be rationed—decisions, in short, about quality,

CALIFORNIA HEALTH DECISIONS
QUESTIONS AND ANSWERS

1. What is California Health Decisions?

California Health Decisions is a project to educate the public about ethical issues in health care and to solicit their opinions and recommendations, so that our health care policies and practices will reflect community values. As medical technology advances, and as costs rise while resources become more scarce, there is an increased need for an organized method of identifying societal values.

2. Where will this take place?

Initially the project is being organized and conducted in Orange County; however, it is anticipated that other parts of California will initiate similar projects. The California Association of Health Systems Agencies has already solicited our help in organizing projects throughout the state.

3. How will the project work?

The project is structured around a series of small group discussions, Town Hall meetings, and a Citizen's Health Care Parliament. The small group meetings will take place in homes, offices, churches--anyplace where people gather--throughout the County. They will be facilitated by a group of trained volunteers and will be held during the months of October, 1985 through February, 1986. A discussion guide will be used to record people's opinions and recommendations.

From February through May 1986, 12 Town Hall meetings will be held in various geographical areas throughout the County. The purpose of these sessions is to report on the concerns and recommendations identified in the small group meetings, to provide further education on key issues and to solicit additional recommendations. Between June and September 1986, reports of the small group and Town Hall meetings will be compiled and shared with the community at large to receive further opinions prior to the Health Care Parliament.

In October, 1986, a Citizens Health Care Parliament, consisting of community representatives, will meet for two days to formulate specific recommendations. These

6. Who is funding the project?

A seed grant of \$15,000 was received from The Prudential Foundation. Donations are being sought from local businesses, foundations, and individuals.

7. How will the public know about the project?

California Health Decisions will publish a bimonthly newsletter available to individuals for a donation of \$5.00 or more. It is hoped that word of the project will spread through those who attend small group meetings. In addition, the media has been enthusiastic about the effort and has published several articles describing California Health Decisions.

8. Is anyone else doing something like this?

California Health Decisions is modeled after a pioneer project called Oregon Health Decisions held throughout the state of Oregon in 1983 and 1984. Since that time, several states have been interested in similar efforts and applied to The Prudential Foundation for grant money. Five states were awarded a grant of \$15,000 a year for two years. Orange County is the only county awarded this grant. The other states are: Maine, Hawaii, Iowa/Illinois, Idaho, and Washington. The time is right for a project such as this and the more activities there are throughout the country the more significant the impact will be, both in terms of recommendations and increased public awareness.

9. How can people get involved in the project?

Those interested in setting up and/or in attending a small group meeting are urged to call the California Health Decisions office at 714/832-1841. The offices are located at the Orange County Health Planning Council, 202 Fashion Lane, Suite 219, Tustin, California, 92680. Other ways to get involved include subscribing to the newsletter, attending a Town Hall meeting and making a donation in any amount.

recommendations will be published and made available to a wide audience, including health care policy makers and providers at the local, state and federal levels.

Following that Parliament, California Health Decisions will continue to exist--as funding allows--to follow up on recommendations and to assist in their implementation.

4. What issues is California Health Decisions concerned with?

Broadly speaking, with ethical issues and health care. Ethics has to do with rights and obligations, with values and principles, with moral choices. "Bioethics" is defined as the study of the moral and social implications of practices and developments in medicine and the life sciences. Not only individual treatment decisions, but broader issues such as the allocation of health care resources have ethical implications. For example, should everyone have access to expensive high-technology medicine, such as artificial hearts? If not, who should get them? Who should decide? How should we divide up our health care dollar between programs to prevent disease and programs to treat it? How should care be financed for the medically indigent?

Other questions concern choices affecting medical treatment. What kind of care is appropriate for seriously ill newborns? For terminally ill patients? Who decides when the most aggressive and sophisticated medical treatments available are not in the best interest of the patient?

In summary, California Health Decisions will be concerned with ethical issues affecting quality of care, access to care, and the allocation and rationing of health care resources.

5. Who is organizing this project?

California Health Decisions was initiated by the Center for Bioethics at St. Joseph Health System, Orange, and the Orange County Health Planning Council. Its activities are directed by an Advisory Board, and the organization has applied for a separate nonprofit status.

LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 5. FACTORS INFLUENCING TREATMENT DECISIONS

October 15, 1985

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 5. FACTORS INFLUENCING TREATMENT DECISIONS

The questions raised by OTA concerning the factors influencing treatment decisions have been answered by a diverse group of experts with a variety of professional backgrounds who practice in multiple regions of the USA or in other nations and in different kinds of care-settings. In addition, their professional perspectives have been supplemented by an organization leader who also has been totally ventilator-assisted for the majority of her productive adult life.

The contributors were:

Augusta Alba, MD - Physiatriist/Neurologist. Authority on long-term respiratory care in the pioneering Howard A. Rusk Respiratory Center, Goldwater Memorial Hospital, New York, New York.

Robert John Byrick, MD - Critical Care Physician/Anesthesiologist. Authority on medical outcomes in an acute ICU, St. Michael's Hospital, Toronto, Ontario, Canada.

Donna Frownfelter, RRT, PT - Editor, Chest Physical Therapy and Pulmonary Rehabilitation. Board Member, Chicago Lung Association; Co-Chairperson, Chicago Lung Association Ventilator-Dependent Adult Project. Director, Chest Physical Therapy, Rush-St. Luke's-Presbyterian Medical Center, Chicago, IL.

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Barry Make, MD - Pulmonologist. Director of Respiratory Care Center, University Hospital, Boston, MA. Former Medical Director, Medical ICU, Boston City Hospital. An authority on home ventilator care for adults. Member, ACCP Ad Hoc Committee.

Walter O'Donohue, MD - Pulmonologist. Chairman, Department of Internal Medicine, Creighton University School of Medicine, Omaha, NE. Chairman, ACCP Ad Hoc Committee.

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY

PROLONGED MECHANICAL VENTILATION

TASK 5. FACTORS INFLUENCING TREATMENT DECISIONSINTRODUCTIONCase Scenario

C.M., in her late sixties, retired after a long and successful career as a teacher. Shortly thereafter, she suffered a severe respiratory infection, which caused her to be hospitalized and ventilated full-time through a tracheostomy. Although she had a chronic disability prior to this acute illness, she was fully ambulatory, independent, and active.

C.M.'s insurance policy paid a fixed rate per day, and her private financial resources were soon almost exhausted. After a period of time, it was no longer to the advantage of the acute medical facility to keep her. Her doctor and rehabilitation therapist wanted, despite her age, to find more for her than the long-term nursing facility which accepted (but did not have a good reputation in caring for) ventilator-dependent people. It was hoped that weaning her from the ventilator would be to her advantage; she would be able to go to a more preferable care setting.

C.M., however, was frightened at the prospect of being weaned. There was no respiratory care program being planned for her which would include mechanical assistance: e.g. oral positive pressure. There was some consideration being given to her living in her own apartment with attendants or nursing aides, combined with technical equipment, such as an environmental control system and wheelchair.

Neither the decision to intervene with a tracheostomy and ventilator as part of her original treatment, nor the decision to wean her from the ventilator, nor the decision as to what kind of life-style she would have after leaving the acute-care facility, was made by C.M. herself. She did not seem capable of making a knowledgeable decision, and she was frightened at the prospect of being without the technology that was sustaining her. In addition, the caregivers (doctors, nurses, therapists, social workers)

were not knowledgeable themselves about the practical aspects concerning lifestyles which were feasible for her situation in her community. The care-givers openly revealed their lack of consensus by conversation and arguments in her presence. This did not contribute to her confidence that she could survive for long outside her present immediate setting. The care-givers did not recognize that her consequent indecisiveness was a logical result of their own. They misread her fears and evaluated her as incapable of making appropriate decisions in behalf of her own interests. A peer-counselor would have provided many answers for both C.M. and the caregivers, presenting them with options and alternatives based on real-life experience. However, no such option was considered.

Community based alternatives do exist for persons like C.M. But they only exist because of the recognition on the part of a few individuals of the issues and their relentless pursuit of legislative change. Such options include independent living services-attendant care, technical equipment, and congregate, accessible housing. The fact that Medicare or private insurance companies do not have services conveniently packaged and readily available, and that they probably do not readily pay for these alternatives, also affected the decision-making options for this elderly person.

Case Scenario

A.V., a masters-level nurse in her mid '70's, has had a professional career in health care involving decades of teaching science at high school, nursing school, and at the college level. Soon after attending a patient with dreaded spinal meningitis, she had a sudden cardiovascular collapse and cardiopulmonary arrest. She was resuscitated by her sister, intubated in the local emergency room, and admitted to a regional ICU for acute respiratory failure which required tracheostomy and prolonged mechanical ventilation (over 3 months). In addition to her pulmonary problem, severe hypoxia (oxygen lack) had resulted in abnormal heart, kidney, and spinal cord function. She made no urine for over 2 months, requiring meticulous attention to her input, output, and weight, as she received daily peritoneal dialysis. She could not move anything but her eyelids, and a world-famous neurologist claimed she never would move again.

After 2 1/2 months of intensive care, a decision had to be made. The coordinating physician (a resident) invited 6 attending specialist consultants who discussed her prognosis and gave their opinion (50-50). The resident,

knowing that further treatment was futile with no urine output, discussed a renal biopsy with the patient who was alert, awake, and informed of the high risk (at this time, A.V. had an increased bleeding tendency). After a discussion (eyelids do permit communication), the decision to do the biopsy led to favorable diagnosis with a prognosis favoring recovery. Soon, movement of the extremities began, and with rehabilitation, A.V. is walking and working today. She continues her volunteer work which, in the recent past, focused on socially-disturbed children. She currently is working with the elderly.

A.V. has given her permission to the OTA to share her feelings about the above experience (Appendix).

Throughout the history of medicine, a basic tenet has been to provide the best possible for the patient. The definition of "best care" was reached by the physician and patient, acting together, searching for the answer to the patient's problems. Decisions were based on moral and ethical principles dear to the physician and patient alike.

In more modern times, decision-making has been clouded by an economic issue. This has been due in part to the recent onset of a budgetary governmental philosophy that arbitrarily allocates a 10% limit of the gross national product to health and welfare issues. Despite the lip service paid to "quality of care being left to the physicians and hospitals" (Senator David Durenberger, R-Minn; Chairman, Senate Health Committee; Author, DRG Medicare Reimbursement System), it is apparent that economics is and will play an unfortunate role in determining the decisions about future care provided to our elderly citizens.

Who, then is the real decision-maker regarding the patient's care: the patient; the physician; the health care system, or the government, which limits payment for services? It is becoming more and more apparent that if cost is the prime mover in making medical decisions, it is the body that regulates financial resources that must bear the prime responsibility for medical decision-making. It is this concept which many people find unconscionable and unethical. It is apparent that if proposed legislation rations health care dollars and services, elderly patients with chronic and expensive illnesses will be closely scrutinized for the cost-effectiveness, rather than the cost-benefits, of their care.

1) In practice, who makes the decision?

The decision to institute prolonged mechanical ventilation is often made on an emergent basis; patients are usually intubated and begun on mechanical ventilation as an acute, life-saving measure. Chronic underlying conditions (diseases, disabilities) may exist, particularly in elderly individuals.

In a few such persons, it is later recognized that they cannot be completely weaned from ventilator support. A new set of decisions must then be made, either to withdraw ventilator support, or to continue ventilation, in a more prolonged fashion, as a life-supporting technique.

In the acute care setting, when a patient is in acute respiratory failure, Make believes that it is always a physician's decision to use mechanical ventilation. The initial physician specialist varies who will decide upon the acute institution of mechanical ventilation in the emergency situation. For post-operative surgical patients, a surgeon or anesthesiologist will make the decision. Alternatively, physicians staffing emergency rooms and

intensive care units are most commonly called. When the decision is elective, the primary care physician generally consults colleagues from pulmonary medicine, anesthesia, and/or intensive care. The initial decision can result in a subsequent situation where long-term ventilation is required. It is less clear who the decision-makers are at this point. In the chronic care setting, where a disease is progressing and respiratory failure is probable, the physician and the patient are the key decision-makers, with input from the patient's immediate family, generally the spouse or children.

Final decisions for treatment must always be made, in Plummer's and O'Donohue's opinions, by the attending physician who is ultimately responsible for all decisions affecting the patient's care. If house staff make the decision, it must be reviewed by the attending physician and agreed upon before action is taken. According to Frownfelter et al, decisions should be made in consultation with the patient, family, and other health care providers. In practice, there is usually a varying amount of input from the "team" members: nursing, respiratory therapy, physical therapy, social service, etc.

At Rancho los Amigos, Prentice states that patients must be "coded" unless they request not to be. The staff tries to ascertain if the patient understands the expected outcomes in order to make an informed choice. However, the decision is made by the patient. At Goldwater, Alba relates that the decision is made by a rehabilitation team, including a nurse, pulmonary technician, respiratory therapist, chest physical therapist,

resident physician, and attending physiatrist, trained in pulmonary rehabilitation. The decision is made, in practice, by the staff physiatrist, the resident, and the patient, with input from other members of the team.

In Canada, major factors influencing treatment decisions in severely ill patients have been concisely reviewed by the Canadian Law Reform Commission (Report 20. Euthanasia, Aiding Suicide and Cessation of Treatment. Law Reform Commission of Canada, Ottawa, Nov., 1983). In practice, competent patients can refuse ventilatory care, even if refusal will inevitably lead to death. The physician's obligation is to inform such a patient fully of all options and consequences. These patients can not be treated against their will, and the role of the family in decision-making is minimal.

Treatment of incompetent persons with initiation of ventilation, weaning, and withdrawal of care in Canada is more problematic. A decision in favor of life is always undertaken if treatment is considered "reasonable and useful". This places the burden on those who would stop treatment, or not initiate life-support therapies, to justify a decision which would result in death. The family is always involved as "surrogate decision-makers" for the patient. Byrick always emphasizes that he wants the family to decide what the patient would have wanted under these circumstances, not what they would want. This substituted consent must also consider quality of life issues.

- 2) In practice, what patient characteristics weigh most heavily in decisions regarding initiation of treatment, weaning, and withdrawal?

Currently, in a dire, life-threatening situation, and without any knowledge of the patient's wishes, all available technology is applied. Elderly patients, in the emergency setting, are given full life-sustaining technological assistance to preserve life (Indihar). However, if time permits, and information can be properly obtained and assessed, there are specific patient characteristics which are considered in the decision-making process.

According to Byrick, the patient characteristics most influential are: competence to give truly informed consent, severity and reversibility of primary disease process, prognostic estimates (see OTA Task 4, Byrick's previous discussion of prognostic uncertainty), response to treatment, and chronic health status (quality of expected life). Alba states that the decision to treat vigorously is strongly influenced by patient's desire to live.

Make believes that the characteristics which weigh most heavily in decisions regarding mechanical ventilation can be categorized into 1) medical prognosis, 2) patient and family wishes, and 3) psychosocial factors. Specifically considered are the prognosis of the underlying disease which requires the institution of ventilation, presence of other underlying or chronic diseases which may/may not complicate use of mechanical ventilation, medical assessment as to whether mechanical ventilation might be able to be successfully withdrawn at some future date, prognosis of the patient with or

without the use of mechanical ventilation, nutritional status, psychological stability, mental status, and quality of life of the patient prior to the institution of mechanical ventilation.

Plummer states that the characteristics which weigh heavily in decisions regarding initiation of mechanical ventilation are: overall health of the patient, the number of organ systems involved, the reversibility of the lung disease causing respiratory failure, mental competency of the patient, and the likelihood of a favorable outcome. Unusually, a patient is placed on a mechanical ventilator with a goal of home mechanical ventilation. Patient characteristics which weigh heavily in decisions regarding weaning include: respiratory muscle strength, the ability to take a deep breath and cough, mental clarity, the reversibility of the pulmonary disease, and the stability of associated medical problems of other organ systems. The same factors are involved with withdrawal from mechanical ventilation and extubation; they include specific criteria for the minimal vital capacity (15cc per kg ideal body weight), inspiratory force (+40cm of water), and acceptable arterial blood gases off mechanical ventilation.

According to Frownfelter et al, Giovannoni et al, O'Donohue, and Prentice, the patient characteristics that weigh most heavily in decisions regarding initiation of treatment are the : primary and secondary diagnosis, nature and severity of the respiratory illness, long term condition, presence or absence of treatable disease, irreversible component of the disease (i.e. terminal carcinoma), prognosis of underlying disease process, special circumstance (patient just out of surgery needing short term support of

ventilation), functional and mental status, age (younger patients seem to be more aggressively treated), financial status (insurance, independent funds), patient and family wishes and choice (although not always asked), patient compliance with health care, and quality of life.

Weaning decisions are mainly based on patient improvement and mechanical ability to maintain a more normal pulmonary function without ventilator assistance (medical stability). Prognosis of the patient will also be considered before weaning is initiated. Weaning is predicated on the measurement of weaning parameters (pulmonary function tests, arterial blood gases) which are used to guide withdrawal of mechanical ventilatory support, and, ultimately, on clinical trials, which determine whether or not mechanical ventilation can be safely withdrawn. The process of weaning may take weeks, and at times months, before a final decision can be made. The final decision is a medical judgement.

Withdrawal from the ventilator is considered when the patient has demonstrated over an extended period of time both strength (i.e. stable pulmonary function and arterial blood gases) and endurance (i.e. most of the day), perhaps only sleeping with ventilator-assistance. There should be the potential seen that the patient can regain adequate function in his/her activities of daily living. In these situations, prognosis is very important, and patient choice is considered. Withdrawal of ventilator support may also occur in patients who are brain dead or who have no potential for useful existence with ventilatory support.

- 3) In practice, what factors influence decisions regarding transfer of patients from one setting to another? (e.g. nursing home to hospital, hospital to home)

Elderly patients that are medically stable do not need to be in a hospital ICU. A transfer to home or a less costly and more appropriate community-based option is desirable. If, how, and when such a transfer is possible depends upon a number of considerations.

Some factors which influence decisions for the transfer of patients from one setting to another are: availability of options; admission criteria; patient acceptance by the facility (long waiting lists); distance from family home and family preference; and the availability of private, public, or personal funds to pay for the alternative setting. Other factors include: physiologic stability of the patient, extent of need for medical input, number of hours of nursing care required; quality of medical care, including nursing and respiratory therapy; patient independence by self-care; prognosis; and quality of life. Thus, the medical status, level of care required, suitability of the environment, and financial factors are the major issues that influence such transfers.

Being home with family members is always the ideal choice. Factors which influence a decision to send the patient home from the hospital include: successful treatment of the acute illness, control of diseases present in other organ systems, possibility of care in the home, and availability of community-based medical services. Transfer of patients from hospital to home usually occurs after it has been determined that the patient's condition

is clinically stable to the point that the patient can be managed outside of the hospital. This requires a team assessment and decision involving the patient, family, physician, and other health care providers.* Resources for care outside of the hospital must also be available, adequately evaluated, and assured of reimbursement prior to discharge.

Nursing homes are often the choice when the elderly cannot be discharged home. Furthermore, when patients are at home, they may be transferred to a nursing home when the physical and/or emotional strain of caring for them 24 hours per day becomes too great for the family to bear (respite care vs. permanent placement). Factors influencing the transfer of patient from the hospital to the nursing home include: inability of the patient to receive adequate care at home, due to the lack of family members present, or inadequate home health services; the intensity of care involved, due to the severity of the patient's illnesses; the amount of rehabilitation necessary before the patient can be cared for at home; and the financial situation.

The nursing home is not able to provide adequate care when the patient is medically unstable. Factors which influence the transfer from a nursing home to a hospital are: superimposition of an acute illness which is unable to be treated in the nursing facility and the deterioration of the

* Editorial Comment: It is my experience that hospital discharge requires a specially-designated core group who understand this process and who can aid their colleagues, the patient, and the family (Goldberg).

overall health of the patient to the degree that a higher level of care is determined necessary for proper management. Ventilator-assisted individuals are transferred from a nursing home to a hospital when they are in need of more skilled care or procedures. However, with the new DRG's, the patient in the hospital is transferred back to the nursing home as soon as they are relatively stable. Often this is too soon, as noted by the quick return back to hospital.

Byrick believes that a major factor influencing decisions to transfer patients from one therapeutic setting to another is the availability of resources. The availability of ventilatory facilities outside acute care settings might alter criteria used to initiate such treatment. Open-ended, government-subsidized funding of such facilities, in poorly organized nursing home centres for the elderly, would increase inappropriate utilization and must be avoided.*

- 4) In practice, what role does age play in these decisions? Is this appropriate?

At the present time, age is not the major limitation on utilization of ventilator care, but rather ICU resource availability often limits its use, forcing appropriate consideration before treatment (Byrick). It must be emphasized that age is an extremely important factor in decisions to

* Editorial Comment: It is my opinion that the development of such options must be under the guidance of experts who understand these realities: professionals, consumers, and leaders from organizations that would be impacted (Goldberg).

institute care as the elderly more frequently have irreversible disease processes and, often, limited chronic health potential (e.g. dementia). Byrick's experience suggests that many elderly survivors did benefit from ventilatory care during acute illnesses; however he suspects very few would be well served by a chronic ventilatory lifestyle (See OTA Task 4).

Make believes that age per se does not play a role in these decisions. Most physicians now recognise that chronologic age alone is not as important as the physiologic age of the patient. Two patients of the same age may have markedly different characteristics. One patient who is 70 years old may be holding down a full-time job, while another patient the same age may be malnourished, withdrawn, and home-bound with severe cardiovascular disease. Nevertheless, the tendency is to recognize that the elderly may not tolerate major invasive therapies as well as younger individuals. Additionally, older people have a reduced life-expectancy because of their age alone. Make believes it is appropriate to consider these realities.

O'Donohue also believes that age alone is usually not a major determinant for the initiation or for the continuation of mechanical ventilation, in or outside of the hospital. More important than age is the disease process itself and the potential benefits to be gained by either short-term or long-term mechanical ventilation. Prentice notes that age plays no role in decisions at his institution; however, priority is given to referrals for admission from younger patients. Plummer states that advanced age usually prolongs the care in the hospital and makes for more complex care at home, because of the co-existence of diseases in a number of different organ

systems. Senility, if present, adds to the complexity of care and influences placement. Age per se usually does not affect placement decisions. Alba agrees that chronologic age per se is not a factor.

Others disagree and believe that age is a strong factor in decision-making. This is inappropriate since the individual patient's condition and prognosis should be the important factors. Age alone should never be the sole factor for any decision. There are young people who should not, in their opinion, be ventilated. Each person and situation should be evaluated on its own merit. Age should play a role in these decisions only to the extent that age impacts on the medical prognosis. They consider age as one, but not the only, factor in the decision.

5) What characteristics of elderly patients may receive inappropriate attention?

No characteristics of elderly patients receive inappropriate attention (Plummer). Others do not agree. O'Donohue states that being elderly may itself result in the patient receiving inappropriate attention. Elderly people may not have visible relatives who are concerned about their welfare; the elderly often may not have a patient advocate. Resources for acute and prolonged care may not be readily available. Giovannoni et al list three characteristics of elderly patients that may result in inappropriate attention by decision-makers when employing long-term mechanical ventilation: age, family support, and financial status.

Frownfelter et al believe that the characteristics of the elderly that may receive inappropriate attention are often behaviors that may be thought of as

typical of the elderly; issues such as sleep disorders, poor eyesight, and poor hearing are glossed over and often disregarded. In a younger population, these problems might be recognized as the cause of dysfunction, but they are often chalked up to "old age" in an elderly population. Alba describes the negative patient who is always finding fault, and the anxious patient; these qualities create inappropriate attention. According to Make, other characteristics of elderly patients which may receive inappropriate attention include the: recognition of other critical disorders; knowledge about the patient's prior life style; evaluation of disabilities related to age; assessment of the health of patient's spouse and family; and awareness of the interaction of family members, including children and parents.

Byrick believes that it is inappropriate for physicians to ignore the elderly patient's expressed desires concerning initiation or cessation of ventilation. These issues should be discussed with such patients before policy options are developed and certainly before prolonged therapy is undertaken. Such paternalistic decision-making may be more common with the elderly when the physician assumes these individuals do not, or cannot, understand the therapeutic options available. It is also inappropriate for physicians to focus on one reversible aspect of a patient's disease (e.g. pneumonia) while ignoring unrelenting irreversible processes (e.g. cancer, dementia). Therefore, chronic health status and quality of life decisions are not only valid but essential in dealing with the elderly.

- 6) How are changes in the patient's condition evaluated, and how do these enter into treatment?

O'Donohue notes that changes in the patient's condition may be evaluated by any member of the health care team and may enter into the decision for either higher or lower levels of care. A patient may at times be transferred to a high level of care based primarily on observations by the nurse or respiratory therapist with agreement by the responsible physician. Transfer to a lower level of care usually takes more of a team approach in assessing all of the needs of the patient in regard to long-term ventilatory support. According to Plummer, all changes in patients' conditions are evaluated by a physician. Appropriate treatment decisions are instituted based upon the history, physical evaluation, and the supporting laboratory data.

In Byrick's experience, changes in the patient's ventilatory condition are evaluated by physical examination and physiological monitoring using such techniques as chest x-rays, serial arterial blood gas evaluations, and lung compliance (stiffness measured using airway pressure generated by the mechanical ventilator). Changes will reflect disease reversibility and response to therapy. In the acute care setting, such factors are important determinants of weaning capability. If improvement does not occur with optimal therapy over a variable time period, withdrawal of ventilation is considered.

Frownfelter et al states that changes in patient condition are evaluated by subjective means, such as clinical observation, and objective means, such as pulmonary function or blood gases assessment. Treatment decisions are

based on these evaluations, which should be performed regularly. Changes in the patient's condition could profoundly affect decisions. If the patient has a change in medical condition, placement may have to be different, level of skilled care may be increased, and even a decision to withdraw support may be made by the patient, family, and/or physician.

At Goldwater, patients are evaluated by an interdisciplinary respiratory rehabilitation team well-skilled and experienced in pulmonary rehabilitation. This team includes a physiatrist, pulmonary technician, respiratory therapist, chest physical therapist, and assigned resident. In addition, a pulmonologist is involved in cases of intrinsic lung disorders. For discharge planning, special staff members including social work, public health nurse, and utilization review are added.

- (7) Are decision-makers sufficiently knowledgeable about the elderly and about ventilation? Are they sufficiently open to the various treatment options?

In general, health care professionals who deal with the chronically-ill are open-minded and supportive to patients regardless of their decision on the use of life-saving equipment. Indihar states that it is a common misconception that physicians force the use of these devices. To the contrary, it has been Indihar's experience that physicians try to educate the chronically-ill patient who might require the life-saving machinery about their disease, prognosis, and likelihood of weaning. This is done in a non-judgemental fashion. The patient is supported in his/her decision, despite the subtle pressures from current legislative trends to deny and ration the health care dollar from patients who are chronically-ill and expensive.

Make thinks that decision-makers may not be sufficiently knowledgeable about both elderly individuals and the use of prolonged mechanical ventilation. The techniques and the management of patients receiving prolonged mechanical ventilation at home and alternate community sites is relatively new, particularly in elderly populations. In addition, the aging population has raised questions concerning many aspects of age so far unexplored; relatively little scientific information is available. On the other hand, Prentice states that decision-makers are sufficiently knowledgeable, and when specific questions arise, consultation is available from experts in geriatrics.

In Plummer's institution, decision-makers have sufficient knowledge concerning the elderly. Usually consultation is requested concerning the patient's ability to maintain spontaneous ventilation, and the physicians requesting the consultation are quite open to the various treatment options available. At Goldwater, Alba states that professionals are open-minded as far as the law permits. Giovannoni et al states that knowledgeable decision-making depends upon the background and expertise of the individual health care practitioners and the hospital's past experience with the patient population. O'Donohue believes that the knowledge and skills of decision-makers varies from institution to institution and region to region. An ultimate goal would be to establish regional centers in which such expertise can exist and to establish adequate and appropriate guidelines for the care of such individuals.

These related experiences differ from that those of Frownfelter et al who believe that decision-makers in many situations may be incapable of effec-

tive judgements. Most medical centers and teaching hospitals have specially trained pulmonary care experts. However, residents may be handling the patients. In smaller community hospitals, it may be the generalist or non-pulmonary physician making the decision. Most generalists and even some pulmonary specialists are not aware of home care options for the ventilator-assisted individual. They are often not open to trying "new methods" or options.

Byrick feels that physicians are sufficiently knowledgeable about the physiological limitations of the elderly. He believes that prognostic uncertainty is the major issue prompting the use of ventilation in circumstances where therapy is ultimately useless. Legal implications of withdrawing such care then become important for the physician decision-maker. Although the physician may be "open to the various treatment options" in these circumstances, widespread availability of home ventilation programs may prompt physicians to delay appropriate decision-making, with costly and uncomfortable results for the patient and family.*

- 8) What is the impact of institutional norms and guidelines re: mechanical ventilation, including "do not intubate" orders and their interpretation?

In Indihar's experience, all hospitals have a mission statement that places first the care of the patient. In no instance has he felt any institutional

* Editorial Comment: I share this concern. A system must be put in place to determine medical necessity and appropriate needs of the prescription and to assure the quality of its administration (Goldberg).

pressure regarding medical decisions. However, with the advent of profit-motivated medicine, the cost factor for the care of these chronically-ill patients will play a major role in the decision-making process.

O'Donohue believes that the question cannot be answered for all institutions. "Do not intubate" orders should be reviewed as part of the quality assurance process for every individual institution. Overall, this order should be reserved for those persons with hopeless disease for whom there is no chance of benefit by initiating mechanical ventilation. The concern is that these orders not be used to deny acute and possibly long-term benefit to patients simply because they have severe disease or because they are elderly. Byrick states that the institutional availability of resources are very important in utilization patterns. The use of "do not intubate" orders and hospital guidelines (re: mechanical ventilation) vary widely. Ethics committees facilitate discussion and awareness of such issues as "withdrawal of care" and consent to treatment.

Different situations are described by contributors to this question. Frownfelter et al remark that institutional norms and guidelines determine where patients are placed in the institution (i.e. ICU vs floor), whether automatic consults go to a pulmonary specialist, and whether patient wishes or "do not intubate" orders are observed. In contrast, Plummer states that there are no institutional guidelines regarding who should or should not receive mechanical ventilation. Generally end-stage cancer patients and those with end-stage lung disease do not receive mechanical ventilation.

"Do not intubate" orders are arrived at by physicians after thorough discussion with the family, and, if possible, the patient. The overall impact is that patients who should not receive mechanical ventilation do not, cost savings are realized, and excessive mental anguish avoided on the part of the patient and family.

Make does not believe that institutional guidelines concerning the use of mechanical ventilations generally impact upon the elderly. On the other hand, more institutions are developing committees to assist in the decision concerning life-supporting techniques. Interpretations of a "do not intubate" are clear. Giovannoni et al state that "do not intubate" order is useful in providing clear direction for staff in terms of a decision-making process completed prior to and in anticipation of an acute event. They serve as established guidelines for this aspect of medical practice. These kinds of orders are by consent of the patient and family and must be frequently reevaluated. At Goldwater, there are norms created by a Professional Practice Committee and Bioethical Committee of the Medical Board. The physician staff there work within the framework of norms and guidelines, and try to affect change in them when needed.

(9) How and to what extent do religious beliefs and cultural values influence treatment decisions?

Byrick thinks that religious beliefs and cultural lifestyle expectations can influence individual decision-makers. Respect for the value of life and individual autonomy varies widely when quality of life measures are considered. Frownfelter et al agree that religious beliefs of both the

physician and the patient play a role. The physician's belief probably plays a bigger role in the decision-making. Patients usually are not asked their religious belief re: ventilator assistance or death. They are usually not cared for by their family physician when in a hospital when on a ventilator. Often the initiation of ventilation is for a medical condition that requires a quick decision on the part of the physician, and time is not spent discussing the patient's religious beliefs.

Make states that religious and cultural beliefs influence treatment decisions, not only by influencing the patient's reaction to mechanical ventilation, but also the reactions of physicians and ancillary medical personnel. Most often, patient's religious beliefs lead them not to accept prolonged mechanical ventilation. They interpretate this as an unnatural form of existence and the tampering of faith as determined by God. Cultural and societal values are also important to patients. Individuals from sophisticated urban centers with sophisticated technological backgrounds are more likely to accept the use of machines to alter their lives.

Indihar has found that most hospital chaplains of all religions tend to be supportive of the patient's decision, regardless if the patient chooses to be ventilated or not. The use of ventilatory support is considered by the majority of religious leaders to be "extraordinary" support; most chaplains/religions do not push the use of these devices to prolong life. The issue of withdrawal of a ventilator, however, is totally different and

much more complex. In most instances, when a patient wishes to have a ventilator withdrawn, the religious and cultural norms consider this to be suicidal behavior, which is currently not acceptable in our society.

In contrasting opinions, Plummer states that religious beliefs and cultural values have little influence on treatment decisions. At Rancho, since the decision is that of the patient, the patient's religion has no bearing on the staff. Prentice is unable to see any trends as far as religion regarding the patient's decision. O'Donohue claims that religious and cultural values affect a minority of patients, but can, in individual instances, prevent patients from getting the maximum treatment benefits that are available under the current health care system. If the religious beliefs are those of the patient, the patient is unwilling for treatment to be rendered, and the patient is mentally responsible, then such treatment is almost impossible to initiate and to continue. If, on the other hand, the religious and cultural beliefs are not those of the patient, there must be a mechanism to allow the patient's wishes and beliefs to prevail. Alba states that the desire to live or not cuts across religious beliefs and cultural values. The patient's own investment in life is of far greater importance - whether he can visualize himself as having a meaningful existence in these circumstances.

The Patient Perspective

SISTERS of ST. FRANCIS

1200 LARKIN AVE.

JOLIET, ILLINOIS 60435

000469

OCT. 7, 1985

MY DEAR DOCTOR ALLEN GOLDFERG,

SEE HOW NERVOUS I AM TO NOT PLACE THE CAPITAL IN TYPEWRITER.

I HAVE BEEN TRANSFERRED TO JOLIET FOR GOOD. THIS IS THE REASON I HAVE NOT ANSWERED YOUR LETTER.

I AM IN CONVENT IN JOLIET NEXT TO THE ACADEMY TELEPHONE 815-744-4106 or 7 address above. please forgive me for error again.

FOR PAST YEAR I HAVE NOT USED THE RESPIRATOR, BUT I WILL HELP WITH INFORMATION.

THANK YOU FOR USING PROLONGED MECHANICAL RESPIRATION.

THANK YOU FOR NOT PULLING THE PLUG ON ME TO END IT ALL

THANK YOU FOR STANDING BY THRU' SPINAL MENINGITIS

TO THIS DAY I AM ALIVE BECAUSE WITH DIALYSIS YOU KEPT ME RECOVERING AFTER FIVE CARDIAC ARRESTS. NOW I WALK WITH SIX FEET, 2 NATURAL AND WALKER WITH FOUR.

I CELEBRATED 74 YEARS SEPT. 16 AND THANK GOD AND YOU I AM VERY INDEPENDENT,

I MEAN I TAKE COMPLETE CARE OF MYSELF IN CONVENT. BECAUSE OF USE OF WALKER,

I PLACE FOOD ON CART AND SHIFT IT TO PLACE OF EATING. WASH MY DISHES ETC.

IN 1970 (DEC. 21) when i contracted spinal meningitis, i never dreamed that i

WOULD MAKE MY GOLDEN JUBILEE. THIS DID HAPPEN HERE IN JOLIET WHEN I FLEW IN FROM CLEVELAND OHIO. OUR COMMUNITY PAID BULK OF MY CARE. AFTER FOUR MONTHS AT PETER

GENERAL IN CLEVELAND OHIO I SPENT TWO YEARS IN RECOVERY CARE IN CONVENT INFIRMARY.

YES, THERE WAS FOOT DROP, VEGETABLE STATUS ALL THIS WHILE THEN SUDDENLY MADE GREAT

IMPROVEMENTS THRU' THERAPY IN CONVENT INFIRMARY CARE. TWICE I WAS HOSPITALIZED

ONCE ST. ALEXIS HOSPITAL AND ONCE AT HOME WITH INABILITY TO REMOVE PHLEBOS THE

RESPIRATORY CHOCEDYL, TAPPING OR CLAPPING TREATMENT PROVED BENEFICIAL. MY DEAR

SISTER MARIE HELPED ME THRU THIS TREATMENT ALSO. NOW I READILY EXPECTORATE.

MY DEAR FR. COLEBERG,
THIS CELEBRATION IN
JOLIET IS OVER AND NOW
I RETURNED TO A ANSWER
YOUR CONGRATULATORY
LETTER. PERSE ENANCE
IS A VIRTUE AND YOU
DID JUST THAT.
FIFTH THREE YEARS OF
LIVING AS A NUN IS
WEVE. I CAN'T BELIEVE
IT. AND YOU ALSO MADE
IT POSSIBLE WITH ALL
THE CARE AND CO-OPERATION
AND YOU DID NOT PULL
THE PLUG. NEVER DID.
I DREAM THIS DAY WAS
JUNE 22nd
WHAT IS IT I SHOULD
WRITE? YOU HAVE A
COPY OF MY ILLNESS.
SMILE WHEN YOU READ
THIS I AM STILL DOING
WELL WITH A WALKER
WHICH MEANS 6 feet/
task for a joke.
MOVED TO MARIE FOR
VACATION TILL SEPT
16th

CATHOLIC

RELIGIOUS LIFE



Sr. Ann



Sr. Consiline



Sr. Agnes

Joliet Franciscan Sisters will observe anniversaries

Two former members of St. Procop Parish will be among 36 Sisters of St. Francis of Mary Immaculate who will celebrate jubilees Saturday, June 22, in St. Raymond Cathedral, Joliet, Ill. They are golden jubilarians Sister Consiline Horak and Sister Agnes (Ludmilla) Vondra.

Among the diamond jubilarians will be Sister Ann Bartos, who taught here for many years, both at St. Procop and Holy Family parishes.

Silver jubilarians will include Sister Kathleen Bushur, a teacher at St. Edward, Ashland, from 1963 to 1965, and Sister Mary Ann Clark, at St. Jude from 1963 to 1968, and St. Procop the following year.

Sister Consiline, who has a bachelor's degree from the College of St. Francis and a master's from De Paul University, has been a teacher in a number of Chicago and Joliet diocese schools. Since 1964 she has been at St. Francis Academy in Joliet, where she now works in the business office and is assistant librarian.

Sister Consiline has a brother and sister, Joseph Horak and Victoria Pavlik, both now living in Illinois.

Sister Agnes now lives at the Vincentian Sisters of Charity Convent in Bedford. She is a volunteer at the Oak Park Health Facility, and involved in Legion of Mary promotion, and in processing stamps to benefit South American missions.

Earlier she engaged in parish ministry at Our Lady of Mt. Carmel, Wickliffe, and in volunteer work for the Wickliffe Country Place Nursing Home.

Her professional career in health care involved decades of teaching science at high school, nursing school and college levels in the Cleveland, Toledo, Joliet and Chicago dioceses. She is a graduate of St. Alexis Hospital School of Nursing; her bachelor's degree is from the College of St. Francis and her master's from De Paul University. Her graduate studies have been at Catholic, Loyola and Notre Dame universities.

Sister Agnes has a sister, Marie Vana, of Seven Hills.

1-216-511-0490
HAPPY DAY THANK YOU

Legal Precedents Re: Life-Support

Beginning with the Quinlan case, several courts have held that the right to privacy in matters concerning one's own body, as developed in Criswold v. Connecticut and Roe v. Wade, is broad enough to encompass a patient's decision to decline life-sustaining treatment under certain circumstances. Courts have also used the common law right to be free from bodily invasion as a supplement or alternative to the constitutional right argument. Many of the most recent cases concerning this issue have involved incompetent persons, e.g., infants and comatose patients. However, there are some cases involving competent persons, and those involving incompetents often contain language referring to competent persons.

Bartling v. Superior Court (Glendale Adventist Medical Center)

This California case, decided Dec. 27, 1984, is quite analogous to the situation now confronted by BLMC. The patient was a 70-year old man suffering from emphysema, chronic respiratory failure, arteriosclerosis, an abdominal aneurysm, a malignant tumor of the lung, and a history of chronic acute anxiety/depression and alcoholism. Mr. Bartling had signed a "living will" and made a declaration stating that he no longer wished to "continue the burden of this artificial existence which I find unbearable, degrading and dehumanizing." He died before the appellate court hearing, but the court ruled on the petition regardless. It held that the right of competent adult patients, with serious illnesses which are probably incurable to have life-support equipment disconnected outweighs the interests of the state in the preservation of life, the prevention of suicide, maintaining the ethical integrity of the medical profession, and the protection of innocent third parties. Note the particular relevance of the following language to the situation at BLMC:

The most significant of these interests is the preservation of life. This is a prime concern to Glendale Adventist, which submitted a declaration to the effect that it is a Christian, pro-life oriented hospital, the majority of whose doctors would view disconnecting a life-support system in a case such as this one as inconsistent

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with the healing orientation of physicians. We do not doubt the sincerity of real parties' moral and ethical beliefs, or their sincere belief in the position they have taken in this case. However, if the right of the patient to self-determination as to his own medical treatment is to have any meaning at all, it must be paramount to the interests of the patient's hospital and doctors. The right of a competent adult patient to refuse medical treatment is a constitutionally guaranteed right which must not be abridged. 209 Cal. Rptr. at 225.

The court in Bartling found that "in the absence of legislative guidance, we find no legal requirement that prior judicial approval is necessary before any decision to withdraw treatment can be made."

In the Matter of Lydia E. Hall Hospital

This New York case, decided October 22, 1982, involved a 41-year old suffering from end-stage renal disease diabetes mellitus, blindness and bilateral amputations due to gangrene. While the patient subsequently lapsed into a coma, the court found that he made the decision to discontinue hemodialysis treatment when he was competent. The court specifically found that the patient made an informed, rational and knowing decision to forego treatment and that the decision did not violate the canons of the Catholic Church. In its decision, the court states that "such a decision must be evaluated and determined on a case to case basis, depending on the factual situation in each particular case." However, there is nothing to indicate whether this evaluation must be done by a court in all instances.

Satz v. Perlmutter

This is a Florida case, decided January 17, 1980. In it, the Florida Supreme Court affirmed that a competent adult patient, with no minor dependants, suffering from a terminal illness has the constitutional right to refuse or discontinue extraordinary medical treatment where all affected family members consent. The court stated that, while the issue was one that would more properly be before the legislature, "absent a response by the legislature, we will be obliged to proceed on a case by case method to meet an inscrutable problem fostered by advances in medical science."

The following cases involve incompetent patients but contain language to the effect that competent patients have the right to refuse medical treatment.

Page Three

Matter of Conservatorship of Torres

This Minnesota case was decided November 2, 1984. The Supreme Court of Minnesota held that a person's constitutional and/or common law right to forego life-sustaining treatment, while not absolute, may be overridden only if the state's interests are compelling. A footnote in the opinion stated that a court order is not required in situations where the attending doctor, the family and the ethics committee are in agreement, however, three justices dissented from the footnote.

In the Matter of Conroy

In this case, decided January 17, 1985, the Supreme Court of New Jersey found that through the doctrine of informed consent, an individual generally has the right to decline to have any medical treatment initiated or continued. While the right is not absolute, the court found that the state interest in preserving life will usually not foreclose a competent person from declining life-sustaining treatment "because the life that the state is seeking to protect in such a situation is the life of the same person who has competently decided to forego the medical intervention; it is not some other actual or potential life that cannot adequately protect itself." 486 A.2d at 1223.

Crouse Irving Hospital v. Paddock

This is a New York case decided January 15, 1985. The court held that every adult of sound mind has the right to determine what happens to his own body, including refusal of unwanted medical treatment. However, the court found that the patient could not refuse blood transfusions after electing to have surgery.

In re L.H.R.

This is a Georgia case, decided October 29, 1984, which held that a competent adult patient has the right to refuse medical treatment in the absence of conflicting state interest.

Barber v. Superior Court of State of California

This case, decided October 12, 1983, involved criminal charges against two doctors for acceding to a patient's family's request to discontinue life-support equipment and intravenous tubes. The court found that a competent adult patient has the legal right to refuse medical treatment; a physician has no duty to continue use of life-sustaining machinery after it has become futile in the opinion of qualified medical personnel; and there is no legal requirement of prior judicial approval before any decision to withdraw life support for terminally ill patients can be made.

Suicide Issue

Several cases discuss the interest the state has in preventing suicide and its relevance to a person's right to decline medical treatment. In Bartling, the court found that disconnecting a ventilator was not tantamount to aiding a suicide because it would merely hasten the patient's inevitable death by natural causes.

In Superintendent of Belchertown State School v. Saikewicz, a Massachusetts court stated that the underlying state interest is the prevention of irrational self-destruction, while the situation presented is a competent, rational decision to refuse treatment when death is inevitable and the treatment offers no hope or cure or preservation of life.

Finally, the court in Conroy found that refusing medical intervention merely allows the disease to take its natural course; if death were eventually to occur, it would be the result, primarily, of the underlying disease, and not the result of a self-inflicted injury.

In addition, rejecting her artificial means of feeding would not constitute suicide, as the decision would probably be based on a wish to be free of medical intervention rather than a specific intent to die, and her death would result, if at all, from her underlying medical condition, which included her inability to swallow. 486 A.2d at 1226.

INTERIM REPORT

November 1984

MEMBERS MAKE PRESENTATIONS TO COUNCIL

In response to the President's letter of June 1984 inviting members to make their views and concerns known to Council, three members were invited to attend Council and make presentations. It was generally felt that this provided an opportunity for members to meet the Council and to clarify misconceptions about the workings of the College.

Council also devoted some time to considering other means by which the activities of the College could be made more visible to both the profession and the public. While no definite conclusions were reached, the Executive Committee was directed to continue to consider the issue as a matter of priority.

The Executive also reported to Council that consideration was being given to holding some of the meetings of the Executive Committee in different parts of the Province. The Executive Committee would then be available to meet with members of the local medical community to discuss issues of current interest. It was agreed that these visits would soon be initiated on a trial basis.

DO NOT RESUSCITATE ORDERS

The College has been concerned for some time about the uncertainty of the legal status of physicians who write an order for a terminally-ill patient that no resuscitative intervention should be made when death occurs. Council considered the recently issued joint statement of the Canadian Nurses' Association, the Canadian Medical Association and the Canadian Hospital Association which was developed in cooperation with the Canadian Bar Association and with the advice of representatives from the Catholic Health Association of Canada and the Law Reform Commission of Canada. It was felt that this joint statement provided physicians and other health professionals with a useful set

of guidelines. The Council supports these guidelines and recognizes that a "Do Not Resuscitate" order for a patient is appropriate in certain situations.

If, in the course of caring for a dying patient, consideration is given as to whether to resuscitate the patient when death occurs, the following protocol should be implemented.

1. Clinical Criteria

1.1 When the patient's condition is such that a decision should be made as to whether a "no resuscitation" order should be written, that condition should be assessed according to certain clinical criteria.

1.2 Those criteria are the best reasonable estimates made by the responsible physician, and a second staff physician where appropriate, about the following:

1.2.1 the irreversibility of the patient's condition and/or the irreparability of the damage it has done;

1.2.2 the length of time that it can be expected that the patient will live with intervention or without intervention;

1.2.3 the consequences of the "no resuscitation" order, i.e. that it may lead to the death of the patient before the time the physician has estimated.

2. Procedural Guidelines

When the clinical assessment justifies the writing of a "no resuscitation" order, the following procedural guidelines are recommended:

2.1 Decision

2.1.1 The attending physician should assess the patient's competency; unless incompetency is obvious, a second opinion should be sought;

Competent patients have the right to make decisions about their treatment, if the patient so wishes, family members may also be consulted;

When the patient is incompetent, the appropriate member(s) of the patient's family should normally be closely involved in the decision-making process.

- 2.1.2 The opinion of nursing staff caring for the patient should be sought; the opinion of other health care professionals involved may be sought, where practical.
- 2.1.3 If the attending physician has doubts about the clinical decision, a second opinion should be obtained from another physician. (There may be circumstances in which a lack of time or unavailability of another physician precludes obtaining a second opinion.)
- 2.1.4 A "no resuscitation" order shall be duly recorded on the patient's record.

2.2 Implementation

- 2.2.1 The outcome of discussions with the patient and the family, and with the hospital staff, should be recorded in the chart along with their views. The physician consultants should record their opinion as a consultant's note.
- 2.2.2 The health care personnel involved in the care of the patient should be informed of the decision taken and of the rationale for that decision.
- 2.2.3 The attending physician and the nursing staff should review a "no resuscitation" order at appropriate intervals.
- 2.2.4 A request by the patient to rescind a "no resuscitation" order should be implemented immediately.
- 2.2.5 If there are unexpected changes in the patient's condition, a nurse or another physician may rescind a "no resuscitation" order until the patient's condition can be reassessed by the attending physician.

3. Care of the Patient

Palliative care to alleviate the mental and physical discomfort of the patient should be provided at all times.

MEDICAL REVIEW COMMITTEE UNDER REVIEW

The President reported to Council that a Tripartite Committee had been established to review policy issues and procedures related to the referral of OHIP claims to the Medical Review Committee and the procedures followed by the Committee itself. In response to criticism from the profession concerning the Medical Review Committee activity, the Executive Committee of the College met with both the Minister of Health and with the Ontario Medical Association and recommended that a Tripartite group be established with senior representatives from the Government, the Ontario Medical Association and the College.

The President informed Council that the Executive Committee had become increasingly concerned that the attitude of the profession towards the Medical Review Committee is producing a distorted view of the College so far as its primary role of developing and maintaining standards of medical practice. The President went on to say that there has been a continuing to be considerable misunderstanding as to how the audit system works and which elements are entirely outside the College's control.

The Tripartite Committee so far has considered issues such as the provision to physicians of an abbreviated personal claims profile which might alert physicians to patterns of billing which could lead to referral to the Medical Review Committee at a later date. The Committee is also considering means by which the assessment of physicians' billing patterns can be accelerated by OHIP so that if a referral is to be made it can be directed to the MRC as soon as the billing pattern becomes questionable in the view of OHIP. A major concern of the profession has been the delay in referral of physicians' claims to the Medical Review Committee which means that a physician may be reviewed for claims extending

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TASK 5
APPENDIX

- 10) Is the elderly patient an active participant in decisions about initiating and continuing care and about weaning? Is she/he able to give informed consent? What are the methods of determining the patient's preference? What is the role of living wills and other advance directives?

According to Make, elderly patients are active participants in decisions concerning ventilation, and they often are able to give informed consent. Age per se is not a limitation in this area. In many cases, physicians who are aware of a possible need for mechanical ventilation or other life-sustaining techniques have discussed these issues with the patient well in advance of the need for the techniques. Patient preference concerning these techniques are known and documented by these physicians. However, in other cases, these issues have not been discussed, patient preferences are not known, and the patient may well be incompetent to give informed consent. This is due to temporary altered mental status because of respiratory failure, and associated hypercapnia, acidosis, and/or hypoxia. Living wills, other advanced directives, as well as the decisions made by close family members are very important in directing care under such circumstances.

In contrast, Frownfelter et al believe that elderly patients are often not active participants and that their preference is not an issue in the decision. Many patients are (or are perceived to be) unable to understand, poor communicators or historians, not "responsible" or capable of making decisions, and difficult to deal with. There is usually more involvement by the patient when the care is more long-term. Living wills are accepted on a state-by-state basis; there seems to be a great deal of variation. This is

confirmed by Alba who states that, although the living will is not a legal document in New York State, the patient's wishes are respected.

Plummer states that mental competence and clarity, regardless of age, are important factors determining whether or not a patient participates in decisions concerning initiation, continuing mechanical ventilation, or weaning. Weaning decisions are made by physicians and discussed with the patient. The decision to extubate requires satisfying the clinical criteria already mentioned as well as a conscious, cooperative, well-informed patient. Informed consent is obtained from the mentally-intact patient regardless of age; interrogation of the patient is the best way to determine preferences. Alternatively, if not able to be interrogated, the family usually can provide information on preferences. Comatose patients can be extubated. Living wills and other advanced directives are honored in Plummer's institution.

Dr. Alba believes that if the patient is fully competent and what is requested is within the law, the request will be honored, including refusal of treatment. The patient has a right to refuse treatment in writing; this is respected in New York State. With an incompetent patient, the families wishes to withhold treatment cannot be honored unless they go to court.

O'Donohue believes that the patient must be involved in the decision for long-term mechanical ventilatory support unless severely mentally-impaired. The goals of long-term ventilator management could never be accomplished in a

patient who is not desirous of this form of therapy. In patients who are acutely ill, the decision for intubation and mechanical ventilation may be made in consultation with family or the nearest living relative. In the acute circumstance, patients are usually not capable of making this decision alone. Living wills or other advance directives would obviously have to be considered in the context of their legality relative to the acute management of patients in respiratory failure. Interpretation may need to be obtained from the hospital attorney in situations where the will is in variance with the medical opinion or the stated desires of the family.

Indihar notes that with the chronically-ill patient, it is becoming very common to ask the patient initially, before consideration of life-saving technologies, to decide whether or not they wish to be placed on a ventilator or cardiac-resuscitated. Interestingly, with time, education, and support, only about 50% of the patients make the decision not to be ventilated or resuscitated. The usual answer is, "If you think I'll make it, please use the machinery."

As already noted, Byrick relates that, in Canada, major factors influencing treatment decisions in severely ill patients have been concisely reviewed by the Canadian Law Reform Commission. In practice, it must be emphasized that competent patients can refuse ventilatory care even if refusal will inevitably lead to death. The physician's obligation is to inform such a patient fully of all options and consequences. Increased patient participation, prior to the need for the institution of ventilation, is

essential. These patients can not be treated against their will, and the role of the family in decision-making is minimal.

Treatment of incompetent persons with initiation of ventilation, weaning and withdrawal of care is more problematic in Canada. A decision in favor of life is always undertaken if treatment is considered "reasonable and useful". The bias must always be in favor of life if the patient's wishes are not known. This places the burden on those who would stop treatment or not initiate life-supportive therapies to justify a decision which would result in death. The family is always involved as "surrogate decision-makers" for the patient. Byrick always emphasizes that he wants the family to decide what the patient would have wanted under these circumstances, not what they would want. This substituted consent must also consider quality of life issues.

11) How and to what extent does practice vary in different parts of the U.S.?

The contributing authors to the above question were selected, in part, because they represent a variety of professional disciplines, care settings, and regions of the U.S.A. Inherent in their individual answers already are a variety of opinions that reflect these regions.

O'Donohue specifically noted that the major differences in practice are related to the size and capability of the institution more than the geographic location. Small and rural hospitals frequently do not have an adequate team to address all of the problems relative to long-term ventilator care. Larger medical centers are more likely to have adequate personnel and

skills. There are, of course, individual exceptions. Some large institutions are not prepared for this form of therapy, and, in fact, may not wish to be involved. Facilities for long-term ventilator care, including necessary support services, are also more likely to be available in urban areas than in small rural communities. Frownfelter et al related that there are tremendous differences even from one hospital to another in the same community. Plummer does not know how practices vary in different parts of the United States, but he suspects that the variations are minor.

(12) What is the impact on treatment decision of existing legislation or particular legal precedents?

All contributors agree that the uncertainty and risk of medical liability is a major issue. Legal precedents are important as most doctors are conscious of their vulnerability for lawsuits (Frownfelter et al). All physicians are quite concerned about the possibility of litigation if incorrect or improper decisions are made (Plummer). However, he feels that treatment decisions are influenced little by existing legislation. Make believes that legislation and legal precedents are very important in influencing treatment decisions, particularly when patients cannot give informed consent, and when the will of the patient is not known. Due to the rapidly increasing number of malpractice claims and rising malpractice premiums, physicians are acutely aware of not overstepping legal boundaries. Indihar states that withdrawal of life-sustaining machines has been a legal dilemma for many physicians due to recent court cases, none of them yet successful, in which the physician,

despite carrying out the patient's and family's wishes, has been sued for criminal intent and murder.*

At Rancho, the rule regarding "no codes" was approved by the County Board of Supervisors; this was because Rancho is a county hospital. According to Prentice, court decisions in California have ruled that the patient has the choice in the question of extension of life. At Goldwater, there is a strong influence of existing legislation and legal precedents in view of the malpractice climate.

Byrick believes that prognostic uncertainty is the major issue prompting the use of ventilation in circumstances where therapy is ultimately useless. Legal implications of withdrawing such care then become important for the physician decision-maker. Legal precedents make physicians wary of limiting the care if the decision has not been fully discussed prior to clinical deterioration. Clarification of the physician's legal status would facilitate appropriate decision-making.

According to O'Donohue, one of the major problems with Medicare legislation is that it does not provide a financial incentive for mechanical ventilation in the home or at alternate community sites. Under the prospective payment system, hospitals clearly have an incentive for early discharge, but the same incentive does not exist for treatment centers outside of the hospital to

*Dr. Indihar is referring to cases such as Barber V. Superior Court of State of California. Please note legal cases provided by Dr. Indihar for review by OTA (Appendix).

accept patients who require mechanical ventilation. Often reimbursement is available only for licensed practitioners in the home where appropriate care could be rendered by less-skilled individuals. Thus, current Medicare policy tends to inflate the cost of home care and often leads to exhaustion of available funds.

When asked to provide additional comments about the effects of current legislation, O'Donohue responded:

"Globally, legislation for reimbursement of Medicare and Medicaid patients favors hospital reimbursement with severe limitations on reimbursement for special care of patients outside of the hospital setting. This becomes particularly important with the increased pressures for early discharge of patients who are more acutely ill. It is extremely difficult to find facilities which are willing and able to accept patients who require mechanical ventilation, primarily because those facilities are not appropriately reimbursed for the type of care they are being asked to render. Funds which are available for home care are also severely limited and at times the regulations for reimbursement of only licensed practitioners tends to inflate the costs when these services could, in fact, be adequately provided by caregivers with less skill and formal training. In other words, the very high cost of skilled caregivers frequently exhausts available funds and results in home care becoming prohibitively expensive. This is not to say that licensed practitioners may not be necessary in some individual cases but there needs to be an option to allow the least expensive care possible to fulfill the needs of the individual patient."

"Clearly, current legislative decisions regarding reimbursement have an impact on treatment decisions in that patients may stay in the hospital longer than necessary if appropriate resources are not available for long term ventilator care, or alternatively patients may be discharged from the hospitals prematurely to sites that are not adequately prepared for the management of this type of individual."

An Invited Commentary

As a supplement to this report, the following commentary was offered by Sister Corrine Bayley, Director, Center for Bioethics, St. Joseph Health System, Orange, California:

"I think that the issue of withholding/withdrawing ventilatory support from permanently comatose patients, while still troublesome, has achieved a considerable amount of consensus in recent years. Several court cases, from the Quinlan case in 1976 to the recent Nejd1/Barber case in Los Angeles have expressed the opinion that life-prolonging treatment need not be provided if it will not benefit the patient. Many hospitals have recently formed ethics committees and have developed guidelines regarding the discontinuation of mechanical ventilation in patients for whom there is no reasonable hope of recovery. In 1982, the American Medical Association's Judicial Council stated, 'Where a terminally-ill patient's coma is beyond doubt irreversible and there are adequate safeguards to confirm the accuracy of the diagnosis, all means of life support may be discontinued.' Several medical associations and joint medical and bar associations have written guidelines affirming that approach."

"One that I support is the recent Durable Power of Attorney for Health Care law enacted in California. This statute allows a competent individual to name someone to make health-care decisions for him/her in case the signer becomes incompetent. Since one of the main things we need to know in situations of medical treatment is what the patient would have wanted, this seems to be a helpful approach."

(13) How does practice in the U.S. compare with practice in selected other countries? Why and with what results?

All involved contributors were asked to comment about their knowledge of foreign experiences. One major contributor (Byrick) related his own personal observations from Canada; Byrick states that the overall Canadian experience is fragmented and poorly described. He has noted that the College of Physicians & Surgeons (Ontario) have prepared and distributed guidelines for DNR orders (Appendix). There is a false assumption that the Canadian malpractice atmosphere is the same as in the States. The major differences are that: 1) there are no lawyer contingency fees; 2) all physicians are insured under a single physician-run Canadian Medical Protective Agency (CMPA); and 3) malpractice issues are seldom settled out of court. If a case comes to court, it must have true merit as malpractice. Thus, the Canadian physician is less concerned about litigation than his/her counterpart in the U.S.A. Byrick concludes that decision-making factors are hard to sort out which determine a DNR order in a critical care setting. However, there seems to be little difference between Canada and the U.S.A. regarding the implementation of mechanical ventilation; the differences, if they exist, are in withdrawal.

Frownfelter et al felt that the United States seems to have little to offer ventilator-assisted individuals compared to England and France. Our health care system and lack of commitment to the needs of the patient with ventilator-assistance accounts for the difference. Plummer believes that the French system provides for a community level of care available to patients who require mechanical ventilation that is not present in our country. Both

the French and English systems seem to be successful because of professional expertise in this area and the patient selection and education which occurs before placement in the home or alternative community site. O'Donohue stated that other countries, which have been most successful in managing ventilator-assisted patients outside of the hospital, have usually utilized a regional approach with regional centers providing expertise for this type of care. Appropriate funding has been made available and a hierarchy of care has been established, including an acute care hospital, an intermediate care facility, and a home care organization which can provide services, equipment, and personnel. For every hospital in the United States to attempt to provide this type of care would be extremely inefficient, and the quality of care would suffer considerably.

In 1983, as a Fellow of the World Rehabilitation Fund, Inc., I (Goldberg) had the opportunity to study the issues facing ventilator-dependent persons in England and France (World Rehabilitation Fund, Inc. International Exchange of Experts and Information in Rehabilitation Fellowship Report #20. Home Care Services for Severely-Physically Disabled People in England and France. Case-Example: The Ventilator-Dependent Person). What follows is a description of the systems in place in those two countries that serve the population as it relates to the OTA question. I will incorporate several comments from Dr. Spencer (London) I specifically requested for this OTA project.

England

The "Responaut Program" is an established system of services available to ventilator-assisted people*. This regional program features the Phipps Respiratory Unit (PRU), a base-unit at St. Thomas' Hospital, London. The PRU provides Dr. Geoffrey Spencer and his highly-experienced respiratory rehabilitation team a site for comprehensive care, preparation for home discharge, and subsequent reevaluation. Of major significance is the PRU home maintenance service, which provides prompt emergency attention and personal surveillance of each responaut in the community. Responauts can be found at home with their families or at a variety of suitable community options. They have available access to learn about, acquire, and use technical aids, which provide great deal of independence. Nevertheless, the elderly responaut may require a group-living arrangement when family members are no longer available or able to provide personal care (Cheshire Home).

The significance of the "Responaut Program" is that a system is in place that makes possible essential and comprehensive institutional and community services and that choices and options are available. This program does not mean that elderly persons are sustained needlessly and/or exist in large numbers because the system is in place. However, when a general practitioner or specialist chooses mechanical ventilation for their patient, there are available resources to enable this to be done properly.

* A responaut is the term coined by ventilator-assisted English people during the early Space Age. Like the astronauts, they wanted to venture out of institutions into the unknown - their communities.

Spencer states that there are major differences between England and America over when, how, and where it is appropriate to use long-term artificial ventilation. Clinical practice in England is more conservative; there is considerable reluctance to embark on long-term ventilation unless there are strong individual positive reasons for doing so. Indeed, part of his job over the past seventeen years has been to advise medical colleagues how best to allow patients receiving artificial ventilation, for whom its continuance seems inappropriate, to die in reasonable peace and dignity. Medical and public opinion in England holds strongly that it is morally, professionally, and socially inappropriate to insist that artificial respiration be continued just because it is possible to do so. In England, the wishes and opinions of the patient, his/her relatives, and medical advisors have overriding priority, regardless of legal considerations.

Dr. Spencer noted that the doctor in charge, after due consideration with all concerned, is the decision-maker in England. He personally thinks that the decision must never be passed to relatives, who are too close for objectivity and live thereafter with the guilt of a negative decision. A positive decision requires a young patient, normally under forty, of at least average intelligence, who will be able to develop intellectual skills and have realistic future objectives in life. Although age is not an absolute factor, a positive decision is seldom made for patients over sixty.

Spencer believes that the prognosis of the underlying disease is the all important evaluation factor. Correct individual evaluation should make the decision obvious. Institutional norms and guidelines do not affect the

decision; the decision depends solely on individual assessment. Finally, Spencer remarks that legislation and legal precedents hardly affect the decision-making process in England. He believes that this is a major difference from the current realities in the U.S.A.

France

The French have a system in place which permits multiple options for the patient requiring prolonged mechanical ventilation. The system features 28 regional associations which provide needed services, care-monitoring, and quality-assurance. Regional associations vary, but are modelled after the original ones created in the 60's: the ADEP (Paris) and the ALLP (Lyon). These original associations today provide essential services to 1200 persons in Paris (ADEP) and over 700 in Lyon (ALLP). Of note, those served are not only ventilator-assisted, but also oxygen and other technologies-dependent. The services were expanded at the request of governmental reimbursement authorities, who helped create the system in the first place.

The regional associations are federated by a national organization (A.N.T.A.D.I.R.) which has recently been responsible for the development of the newer associations. In addition, A.N.T.A.D.I.R. fosters national research and surveys providing needed data and analysis by the regional associations (to improve services), and by the government (to determine public policy). As a result of medical, technical, social, and administrative studies, the number of ventilator-dependent patients are known, and many of the questions posed by the OTA have been answered in France. For example, at a recent national meeting in Lyon (3/85), it was stated that there are

approximately 50,000 people in France with chronic respiratory insufficiency who require specialized care. Of these, 12,000 persons at home receive respiratory care for 12-24 hours/day at home. Among this subgroup are 1200 people who require prolonged ventilator-assistance.

A.N.T.A.D.I.R. is currently revising the future procedure for home ventilator care as a national policy. As before, all decisions will be made by a prescribing physician (generalist, specialist), with the patient and family involved. This is vital because, in France, the home care of the ventilator-assisted person depends upon the role of the family and self-care. A defined prescription will be standardized; each will be reviewed by a physician in a regional association. Only after modification or approval will the prescription be funded and implemented. The association will continue the surveillance of the patient at home to be certain that the prescription is medically-appropriate and delivered as intended. Previously, it was possible for a physician to write prescriptions directly to the reimbursement authority and to have it filled by a pharmacy or vendor. Because this proved to be inappropriate and expensive, this new process will be established by A.N.T.A.D.I.R. This will be only one of many cost-saving measures established by A.N.T.A.D.I.R.; others include negotiation with manufacturers and reimbursement authorities, mass-purchasing, inventory and depreciation reduction strategies.

In France, the physician and family have a choice of options which include services at home, independent living center (foyer), secondary intermediate center (transitional care), and respite care. In addition, the French government has authorized officially a personal care attendant to supplement family members. These options are viable for the elderly. At the 3/85 Lyon meeting, the French were asked by the English if they would provide such services to a person over age 65. The answer was "oui". When further questioned, the response was, "mais, c'est normal!" It is clear that cultural factors play a large role in France.

The Netherlands

Other nations have begun to recognize that the ventilator-assisted individual represents a medical and societal issue to address at the national level. In August, 1985, all identified physicians that care for such patients in Holland were assembled at the State University, Groningen, to attend a round-table conference about these realities. Under the direction of Henk J. Sluiter, M.D. Professor of Pulmonary Diseases, and Head, Respiratory Care Unit, the meeting assembled the following data and conclusions:

- 1) Number of home-care patients (ventilator-dependent): 50
- 2) Number of chronic ventilator patients in hospital or specialized units: 48
- 3) Nearly all patients are ventilated only part-time during 24 hours.
- 4) Indications or criteria for this treatment: not standardized.

- 5) Total number of patients who should receive the treatment: unknown, depends on the criteria of each center.
- 6) Marked differences between the different centers in:
 - a. diagnostic categories;
 - b. therapeutic modalities. (e.g. Utrecht: nearly all patients via tracheostomy (TIPPV); Groningen: many patients with cuirass ventilator).
- 7) Only an exceptional patient up to now treated with oral positive pressure ventilation (MIPPV).

These preliminary data have been offered to the OTA with the understanding that proceedings will be available in late 1985.

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 6. CONCLUSION AND IMPLICATIONS

October 15, 1985

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LIFE SUSTAINING TECHNOLOGIES AND THE ELDERLY
PROLONGED MECHANICAL VENTILATION

TASK 6. CONCLUSION AND IMPLICATIONS

The questions raised by OTA in Task #6 were asked to selected contributors of previous tasks and other appropriate experts who responded to each question as an original contribution. Their answers were collected, reviewed, and organized by Ed Roberts, Founder, World Institute on Disability, and his staff, especially Patrick Connally, M.A. When possible, efforts were made to relate conclusions and implication to information presented in the preceeding tasks of the report in order to provide qualification and further amplification.

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Ed Roberts, Founder, World Institute on Disability. World authority and public policy expert on issues concerning disability and the independent living movement. A ventilator-assisted person during all of his productive adult life.

1) How important and how urgent are problems related to mechanical ventilation?

In an attempt to promote cost-containment, the costs of providing critical care for the elderly has come under increased scrutiny. The critically-ill person uses enormous quantities of hospital resources (Task 4 - Byrick). Great amounts of time, space, personnel, and highly sophisticated equipment are used to sustain life and initiate the recovery of the critically-ill. An important aspect of critical care is ventilator support, and there is a great deal of discussion in medical, political, and lay circles as to the cost and the efficacy of this care (Task 4 - Byrick). Until now, no comprehensive survey initiative has been taken to determine utilization and cost (Task 3).

Many persons, professional and the laity, think of ventilator use for the elderly as needlessly prolonging the life of terminally-ill patients. However, ventilation is not only used to sustain life but also to initiate recovery and to allow the elderly person to have a more productive life (Task 2 and 4 - Alba and Indihar).

The decision to put the terminally-ill individual on a respirator has generally been exclusively a medical one, with little or no thought to the long-term effects on the person or his/her family. The literature and comments from this study predict that this practice will decrease (Task 3 and 5). Many physicians before ventilating a patient are now considering the age, overall condition, and whether prolonged ventilation is the choice of the family and person. Many individuals are requesting

"no code" through the making of a "living will". Physicians are seeking informed consent from the person if competent or from the family if the person is incompetent (Task 5).

The decision to place a person on a ventilator to initiate recovery is less difficult to make. However, there are several psychosocial aspects of the consequences to consider (Task 4 - Byrick, Pfrommer, Laurie). If the person will only be ventilated for a short time, there are few problems. If not, questions of placement become relevant. There are a limited number of chronic care facilities available to care for ventilator-assisted individuals (Task 3), and most families would need extensive training to care for the patient in their home. One of the greatest fears of the elderly is the fear of dependence. In this instance, the ventilator assisted person is dependent not only on a caregiver but also a machine.

The important issues of mechanical ventilation to the elderly seem to be more psychosocial than medical: 1) the desire to have some control over the decision to prolong their lives and 2) the fear of the dependence on their families that prolonged ventilation could create (Task 4 - Pfrommer, Laurie). The cost issues, which may or may not be of concern to them, could be eased with responsible informed decisions to ventilate and the development of alternative placements from ICU's to home or chronic care facilities (Task 5).

In view of the current legislation and hospital reimbursement policies (DRG Prospective Payment System), it is necessary that the issues sur-

rounding the use of mechanical ventilation for the elderly be resolved (Task 5 - O'Donohue). These issues, which currently apply to the elderly, may also be applied to younger patients requiring life-sustaining technologies. If the Medicare prospective payment system reimbursement is applied to Medicaid (welfare) medical payments, the tendency will be to deny this type of care to any chronically-ill patient. For instance, the DRG payment to a hospital for a patient with chronic obstructive lung disease is only approximately 10 days; if the patient requires ventilation for ventilatory failure, the hospital gets absolutely no further reimbursement until hospitalized for approximately 30 days, at which point a minimal daily reimbursement is given to the hospital. This usually does not cover the hospital's expenses. Hospitals cannot be expected to underwrite the care for these patients. Is there a subtle message that such legislation is giving to the health care professional: do not waste the health care resource dollar on the chronically-ill patient, regardless of age, who needs a respirator?

Another urgent issue is the prolonging of death by abuse of technology (Task 4 - Alba). Many people may not be rendered brain dead by severely decapitating cardiopulmonary conditions, but may remain either in a semi-comatose or comatose condition for many months or even years. With the law as it stands today, such patients must be maintained on ventilators until death from other causes. Is this not another example of public policy that serves neither the dignity of the person nor the ethical standing of the medical professional who must participate in prolonging death rather than sustaining life?

2) To what extent do these issues have special significance for the elderly?

As the population ages, there is a higher incidence of cancer and chronic disease which may precipitate ventilatory failure. This creates increased costs due to long-term hospitalization in expensive ICU beds which may be exacerbated by the lack of reimbursement in some states for chronic care outside the hospital. If reimbursement is available for home care, this is a viable option. Where independent living support services are available, people can live in the community (Task 4 - Pfrommer, Laurie).

Many acute diseases causing death and disability during the early and productive years of life are no longer problems, and chronic diseases particularly in the elderly population have become increasingly more prominent. These chronic diseases often require complex and expensive diagnostic technology to define them, but the medical interventions which are available serve primarily to maintain or preserve function.

Respiratory and intensive care units have increased the survival of all patients with respiratory failure. However, the survival of those who require prolonged ventilator assistance is small in number and achieved only at great cost. Davis⁽⁴⁾, however, stressed that patients with only lung disease had the lowest immediate, one year, and two year mortality, as well as the lowest charges per hospitalization compared with other patients in his institution on receiving similar ventilator support. Furthermore, Davis felt that since all survivors of the

critical episode (respiratory failure) have a 50/50 chance to live two more years, it is medically and ethically appropriate to continue to provide supportive care for these patients, if we are going to provide critical care for the seriously-ill older adult population.

In several studies on patients receiving mechanical ventilation, a significant percentage were 60 years and older:

Davis, et al (4).....	Mean age 66.7
Sukumalchantra, et al (10).....	Mean age 62
Moser, et al (9).....	Mean age 60.6
Kopacz and Moriarty-Wright (8).....	27% over 65
Fischer and Prentice (5).....	41% over 65
AART study (1).....	34% over 65

In Campion et al.,⁽³⁾ once patients were admitted to the ICU, the older they were, the greater the probability that they would be placed on mechanical ventilation. Fourteen percent of the patients 55-74 and 19% of patients 75 and over-admitted to ICU were intubated and mechanically ventilated during their course of treatment.

Age of the person plays a critical role. Infants and children usually have parents who care very much about them and are prepared to make financial sacrifices for them (although infants are usually born to young people with limited financial resources). Old people are particularly vulnerable because they are more likely to be alone, more

likely to be personally powerless, and more likely to have limited financial resources.

Of special significance to the elderly ventilator-assisted individual is the need for in-home service, such as personal care assistants (Task 4 - Pfrommer, Laurie). The older ventilator-assisted person usually cannot be cared for at home by his/her spouse as a child can be cared by his/her parent. The spouse will often have medical problems which limit their physical capabilities (i.e. arthritis, heart disease). In many instances, no immediate family is available to assist elderly persons on mechanical ventilators. As a result, there are fewer advocates for the use of ventilators by elderly as compared to advocates for the use of ventilators by children.

3) What issues can be settled by professional, community, or private sectors (without congressional actions)?

Some issues can be settled by professional, community, or private sectors. They can be grouped under the following categories: continuum of care, funding policies, accessibility, economic incentives, standards of care, better services and equipment, "living will", and small-scale demonstration and research.

A continuum of care for respiratory-dependent elderly can be developed by designating selected regional centers of expertise dedicated to this problem and by establishing a regional system to assure fully-integrated services in the community. This can both be accomplished regionally and integrated at the national level as shown in France (Task 5).

The professional, community, and private sectors' funding of the concepts of volunteerism and training could support Independent Living Centers which would assist the elderly ventilator-assisted person as they have post-polio and spinal cord injured consumers. Independent Living Centers, such as the Center for Independent Living in Berkeley, California, offer a wide-range of services, such as peer-counseling, attendant training, attendant referral, and independent living preparation.*

Funding is not easily found to pay for essential caregiving, durable medical equipment, and home renovation required by the ventilator-assisted individual. Private third party payors have set precedent by reimbursing on an individual case basis what personnel and equipment are deemed necessary to properly support an elderly ventilator-dependent person (Task 4). It would be both cost-saving and safe if such payors would allow non-professional personal care attendants to support the care of families and professionals. It would also be cost-effective to all sectors if existing building codes stressed accessibility and adaptability for all Americans (Task 4).

Another factor in funding is that there presently exists no economic incentive for professional, community, or private sectors to organize

*Berkley Planning Associates, Susan Stoddard, Project Director. "Evaluation Report on the State's Independent Living Center, Funded by AB20Y". Submitted to California Department of Rehabilitation, March 1980.

support services for the ventilator-dependent person. These sectors generally look to Medicare to take the lead. It is recognized by all that comprehensive reimbursement is required in full for those resources necessary to adequately support an elderly ventilator-dependent person in a home setting or alternative environment.

The consumer, professional, and lay community must have input in setting standards for treatment and guidelines for care. There will be many exceptions, as each case must be handled individually; a "cookbook" approach is inappropriate. Those that actually deal and live with the care should determine the standards based on their experience and insights. Ventilator standards of quality must be developed and used.

Better respiratory equipment is needed. What exists is often undependable, with many breakdowns that result in life-threatening situations; only experiences from centers of expertise seem to have better results (Task 2 and 4 - Alba, Indhar). There are few consumer options to choose for a home ventilator. It would be cost-effective to all sectors if there were more competition among home care services and medical equipment dealers.

The "Living Will", being able to die with dignity, are issues the community and professionals must address. "When to pull the plug" must be established on an ethical, medical, and individual basis, or policies will be determined by economic realities (Task 5).

Nongovernmental sectors can raise such issues to public awareness. They can explore and experiment with alternatives for reimbursement and the provision of care, as the recent American experience with the hospice movement has shown (Task 4 - Pfrommer, Laurie). They probably can provide some funding for small scale demonstrations and their evaluation.

4) What issues require congressional actions?

Currently, individuals that have a potential for a full and satisfying life with the assistance of a ventilator find only a few limited options for care. Congress should bring together all parties involved with ventilator use issues and provide leadership in their resolution. A priority is for Congress to hold hearings and fund research to establish demonstration projects to determine how to best provide services for ventilator-dependent individuals. A normative approach must be taken to devise a continuum of care, and, at the same time, cost-out the different alternatives to determine the most cost-beneficial ones.

Immediately, Congress must begin by creating a new Medicare/Medicaid benefit that reimburses services provided to elderly ventilated people. At first glance, this may seem like an added cost measure. However, this could lower cost in the long run by reducing the number and duration of much more expensive hospital admissions which result from medical instability (Task 2).

Title VII of the Rehabilitation Act of 1973 mandated Independent Living Centers. Congress should fund these centers to demonstrate cost-bene-

ficial home care. Services for people with severe disabilities could be applied to the ventilator-dependent elderly. This could be one of many demonstrations showing that what would put in place for one population could serve others with related needs.

Congress should consider a Federal program to establish regional medical centers that deal with special respiratory problems and prolonged mechanical ventilation (Task 5 - O'Donohue). These centers could be along the lines of the former polio centers of the '50's or the current French system. Congress should also authorize the National Institute on Handicapped Research to award contracts for the development of less-expensive and more reliable portable ventilators.

5) Is it feasible to propose treatment guidelines for mechanical ventilation?

Treatment guidelines must be flexible enough to allow for individual choice (Task 5). Guidelines are a tool to establish a standard of treatment throughout the country. They should include a description of when living at home will be successful or when other options may be more desirable. The American Thoracic Society has already suggested guidelines for physicians to use in prescribing respiratory equipment at home in an attempt to reduce unnecessary use of this equipment.* The

*American Thoracic Society. Home Care of Equipment for Patients with Respiratory Disease. Amer. Rev. Resp. Dis. 115 (Suppl):893-895, 1977.

American College of Chest Physicians has created an ad hoc task force to develop guidelines for ventilator care in the home and at alternate community sites.*

The establishment of treatment guidelines would assure that: a) treatment goals are determined; b) all appropriate resources required to achieve the goals are identified; c) appropriate and competent health care personnel are made available; and d) a basis exists for the justification and documentation of needed support services and other long-term considerations. Furthermore, standards of care would provide a general approach to diagnosis and management so that clinical professionals not familiar with care issues would have proper guidance.

There is great debate that treatment guidelines are necessary. There are concerns that treatment guidelines could become a euphemism for "rationing health care". Some people feel once ethical and moral decision making is left to the legislative process via "treatment guidelines", the very fabric of decision-making for the individual is lost. Others believe that they will be abused in the current litigation climate.

*All members of the ACCP task force are contributors to this OTA Report. Guidelines are anticipated by early 1986.

6) What aspects of mechanical ventilation and the issues it raises call for additional research?

There are a number of areas in which research must be conducted:

- biomedical research concerning the conditions that make reliance on optimal mechanical ventilation necessary and appropriate, and those under which weaning is viable;
- successful weaning strategies, and the role of family and social support in this process;
- the relative advantages and disadvantages of medically, financially, and socially varying arrangements for the provision of care;
- the social impact on the patient and family of different institutional and community arrangements for delivering health care;
- factors in the social infrastructure that seem to aid or to hinder successful home care;
- the impact on hospital staff, families, volunteers, or paid helpers of the task of caring for patients who often do not get well or whose health is likely to be seriously impaired despite good care;
- the meaning for patients, family, staff and others of the reliance on mechanical support; comparisons with data from situations involving renal dialysis or mechanical hearts. Since reliance is likely to grow, there is need to understand now the relationship that develops among patients and others and mechanical equipment.
- study of the impact of previous counselling and the use of role models by consumers;
- the development of simple, more reliable, easy to maintain, and less expensive home ventilators; and

- research on outcomes of long term care. Although there have been some long-term studies of mortality after discharge from ICU's, there are few describing long-term functioning following discharge on mechanical ventilation. Studies on survival are medically-oriented, and they do not consider quality of life issues for the person nor his/her family. Few studies of survival compare persons on mechanical ventilation with patients with similar degrees of impairment not on mechanical ventilation. Experience suggests that basic incidence and prevalence data are not even available on this population. In this regard, evaluation of other developed nation's programs would be useful.

7) What is the potential for reducing the rates of lung disease and other conditions leading to ventilatory insufficiency and failure in elderly persons? What potential problems can be prevented?

There are at least two approaches to these questions depending on the scope of preventative means that could be implemented.

If the scope of this study is limited to chronic ventilator-dependent persons, then prevention should be aimed at minimizing reinstitutionalization. In order to prevent readmitting people to the hospital on a recurring basis, it is suggested that a system of monitoring care in the community be established. Such monitoring would include not only the operation of the equipment, but also the person's condition, and the home situation in which the person lives. Any change in one of those three areas may result in the need for readmission of such a person to a

tertiary care institution. On the other hand, if a proper monitoring system were in place, then the justification for a support service would be identified in an objective and timely fashion, and care could be coordinated, quality-assurance guaranteed, resulting in significant cost-savings as has been demonstrated in France (Task 5).

If prevention is applied generally, then environmental issues like air quality become important. Any means that lowers the incidence of lung disease could be called preventive. Accidents account for spinal cord injuries that leave persons in need of ventilation assistance, so safety become another preventive issue. Many diseases such as A.I.D.S. or polio will create the need for mechanical ventilation. Primary prevention of disease must be fully implemented. The World Health Organization notes the addition of 500,000 post-polio individuals to the world population every year; immunization becomes a preventive means. There is a large population of Latin Americans in the United States which never has received proper immunization.

Primary and secondary prevention are critical, and should not just be a response to acute intervention. Good health and nutrition will become even more important as a preventive means because, in the next 50 years, it is estimated that the number of Americans 65 and over will more than double. The census bureau projects that this population will reach 65.9 million by the mid-2030's. Even with medical advances, a segment of the elderly population, especially those over 85, will have disabling diseases. Today about two out of three of all people with disa-

bilities are elderly. Among these elderly are increasing numbers of people who will need to add ventilation to their lives.

8) What particular issues and problems should be priorities for public attention?

This basic issue raised is one which society can solve by indicating strongly its desires relative to the allocation of resources. For instance, is it sensible that an industrial nation should allocate only 10% of its gross national product to health and human services? Is it sensible to ration health care to the elderly and chronically-ill? Is it appropriate not to reimburse hospitals for their expenses in caring for these persons? Society must decide the answers and deliver their answers to the responsible legislative bodies, who bear the ultimate responsibility to transform society's wishes into law. It appears that the present legislation is not understood by the vast majority of Medicare/Medicaid recipients.

Major initiatives must be taken to create an informed public opinion (Task 4). The public must understand that the Medicare system, as it is administered today, is by and large inefficient for both assuring quality of care and cost-savings. In order for the reimbursement system to survive the future, it must undergo a transformation. Revisions should include, but not be limited to, an examination of all current benefits along with cost-identification and determination of outcomes. The public should also know the need for the creation of new benefits and the review of current eligibility requirements so that with new medical

advances appropriate care will be given in the appropriate environment. As it stands today, there is a great incentive for patients to be admitted to a hospital in order to receive their benefits when it might be possible for those patients to avoid hospitalization.

The ventilator-assisted person represents more than a complex medical issue; their situation involves social problems whose solution will have major impact on health care and social policy. Thus, public attention should be directed to awareness of the needs of this patient population. Funding issues are a priority. Alternatives to hospital intensive care units should be found. Options should be available to this population: hospitals vs. home, extended care facilities, stepdown units, and rehabilitation and transitional care facilities. Regional care centers should be developed with expertise in dealing with this population. Community alternatives to home must be considered: congregate housing, respite care, and medical foster care. Issues of quality of life on the ventilator as opposed to weaning at all costs should be addressed. The capabilities and productivity of an individual that is ventilator-assisted should be truthfully presented and erroneous stereotypes linking aging and death should be changed. Whenever life-support systems are involved, there will be need to encourage public discussion as to the circumstances under which society will support the allocation of resources for persons who will not recover, or under which there will be pressure to end the use of this equipment.*

* Editorial Comment: "Town Hall" meetings such as California Health Decisions Involving Citizens in Health Care Choices (Sister Corrine Bayley, CSJ) will be good models for other communities to follow (Task 4).

Finally, public attention should focus on establishing a long-term care system. This type of system is essential for quality of life to individuals who are disabled and/or elderly. Substantial savings in acute care costs could be realized by such system which could provide mechanical ventilation in a more timely and appropriate manner.

9) What existing problems may be amenable to public policy change?

At the present time, given the low incidence and the low profile of the related problems, it is likely that all issues are amenable to change. Those most amenable for public policy change are suggested:

- 1) The ventilator-dependent consumer must function as a member of the team that determines care. He/she should have access to peer counseling and role model direction. Programs could be established like the systems developed for polio at Rancho los Amigos and Goldwater.
- 2) The current system of reimbursement should be adapted as it applies to the chronically-ill, ventilator-dependent patient. A DRG exception should be provided to centers of expertise that have a proven track record of care given in a cost-efficient manner. Payments should include a variance for severity of illness; this currently does not exist.
- 3) A legal standing for the "living will" or similar initiative should receive national affirmation.

- 4) A person should not have to be hospitalized in order to receive a benefit, but should only have to document needs. In this way, a ventilator could be used before an acute crisis and in a cost-saving setting.
- 5) Hospitals should be adequately compensated for their cost to provide care for each patient, provided they maintain proper accountability.
- 6) Adequate payments should be provided for home care support personnel, particularly respiratory therapists, nurses, and personal care assistants who are required by ventilator-assisted persons at home.
- 7) There should be better provision of care for the chronic, ventilator-dependent patient, similar to the hospice program currently allowable under Medicare payment systems.
- 8) Education and training of doctors, staff, family, and consumers, and other concerned persons in the use of technology and philosophy of independent living should be made available. This would be possible by establishing and strengthening of Independent Living Centers patterned after the Center for Independent Living, Berkeley, California; creating designated centers of expertise like at Goldwater and Bethesda Lutheran Medical Center; and creating documentation resource centers such as those operating in France.
- 9) A systems approach is necessary to coordinate all the available resources from the private, public, voluntary, and governmental sectors. The issues are too complex and the involved organizations too numerous to expect the spontaneous resolution of problems discussed in this report. Needs that can be addressed by such a system in-

clude overall care-monitoring, outcome-determination, quality-assurance, and cost-accountability.

- 10) The need for public awareness and research to resolve unanswered questions raised in this report requires a designated body which should include professionals, consumers, and involved groups who are knowledgeable about the issues. Such a body could be responsible for determining priorities, encouraging demonstrations, and evaluating research initiatives.

10) What are some of the public policy options?

- 1) The first option is to leave the system as it is. Let the issues percolate until they become a higher priority ("the ostrich approach").
- 2) The second option is to leave the system as is, but add flexibility in reimbursement, more consumer involvement, and resolve DRG issues ("patch it").
- 3) The third option is to initiate and evaluate demonstration projects that gradually affect and incrementally change the system to provide a more cost-effective continuum of services ("change it").
- 4) A fourth option is to create a system providing a continuum of services that would deal with the issues of ventilator use in terms of long-term care as opposed to the present model of acute care ("fix it").
- 5) A final option would be a "Right to Breath" Law. Such a law would provide a comprehensive system for the ventilator-assisted individual ("legislate it").

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HEMODIALYSIS, PERITONEAL DIALYSIS, AND RELATED THERAPIES
FOR RENAL DIALYSIS AND THE ELDERLY/TECHNOLOGY
Contract #533-5850.0

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A. BACKGROUND AND HISTORY

1. Hemodialysis

Thomas Graham, one of the early scientists to work in the area of colloid chemistry, was the first to show that crystalloids would pass through a semipermeable membrane while colloids did not, and named this process "dialysis" (1). However, it was not until 1913 that Abel, Rowntree, and Turner developed the first artificial kidney which was used for removal of solutes from the blood of experimental animals through a semipermeable membrane (2). The membrane consisted of celloidin tubes, the dialysate was saline or artificial serum, and the animal's blood was anticoagulated with hirudin obtained by crushing the heads of leeches. It is interesting that Abel and his co-workers suggested flattening of the celloidin tubes to increase their efficiency, reminiscent of present-day coil dialyzers, and noted that very small tubes "would undoubtedly prove valuable," thus predicting hollow fiber dialyzers. Abel and his colleagues carried out a series of experiments, developed a number of pieces of apparatus, and were interested in the possibility of using their new invention, which they had named an "artificial kidney," in humans (3). Nevertheless, the first human dialysis was not performed until 1924 by Georg Haas in Germany (4) using celloidin dialyzing tubes and hirudin as anticoagulant in what was essentially a larger version of the Abel, Rowntree and Turner device (5).

Over the next few years two important developments made dialysis of humans more feasible. First was the production of purified heparin as anticoagulant, and the second was development of a

commercially available cellophane membrane. As a result, in 1937 Thalhimer constructed a dialyzer similar to the Abel dialyzer using cellophane and heparin, and used this experimentally in dogs (6). However, the surface area was not sufficient and he did not pursue this further.

The first practical artificial kidney was developed by Kolff in Kampen, Holland, during the second world war. Kolff's dialyzer was a cylindrical drum on which was wound a 30-40m length of cellophane sausage tubing which was perfused with the patient's blood through a rotating coupling that was based on the Ford automobile water pump. The lower half of the rotating drum was immersed in a stationary tank containing a large volume of dialysis fluid. Blood was propelled through the tubing by rotation of the drum so that a blood pump was not required. Kolff attempted his first human dialysis in February 1943 but the patient died (7). A number of technical difficulties had to be overcome such as membrane leaks, hemolysis, blood line disconnections and hemorrhages; but Kolff and his colleagues continued their efforts, concentrating on treating patients with acute reversible renal failure. However, it was not until their 17th patient was treated in 1945 that one survived who clearly owed their life to treatment with the artificial kidney (8). Following the second world war, Kolff rotating drum machines were sent to London, New York, Montreal, Amsterdam, and Poland. Meanwhile, Murray and co-workers in Toronto had also developed an artificial kidney which was first used in 1946 (9). The Kolff machine was

modified at the Peter Bent Brignam Hospital in Boston (10) and was used in a number of centers around the world to treat acute renal failure.

Other dialyzers were developed following the second world war. Alwall in Sweden devised a stationary upright drum dialyzer which was the precursor of coil dialyzers (11), but the prototype of the present-day coil dialyzer was developed in 1953 by Inouye and Engleberg in Philadelphia (12,13). This used cellophane tubing wound in a helix around a stainless steel core, with plastic mesh acting as a spacer. The coil, with a surface area of $0.9m^2$, was placed in a pressure cooker through which dialysis fluid was recirculated from a 50L tank. Blood was circulated with or without a blood pump, and ultrafiltration was regulated by controlling the rate at which dialyzing fluid was drawn into the dialyzer by a water pump. This was the model for the "twin coil kidney" developed by Kolff and Watschinger (14,15) and which was eventually produced commercially by Travenol Laboratories in the United States, gained rapid popularity, and was very widely used in the 1950's and 1960's. Its disadvantages were that it required a blood pump, had a high blood pressure in the extracorporeal circuit, required priming with blood before dialysis, and used a large open tank of dialysis fluid which could easily become contaminated.

Other dialyzers were developed during these years. MacNeill and co-workers in Buffalo devised a dialyzer using short lengths of flattened cellophane tube which was the prototype of parallel flow dialyzers (16,17), and Skeggs and Leonard at Western Reserve developed

a similar dialyzer (18,19). This latter used the countercurrent principle in which dialyzing fluid passed through the dialyzer in the opposite direction to the blood.

Throughout the 1950's and early 1960's dialysis was used primarily for the treatment of acute renal failure, and while a number of units continued to use variations of the original Kolff rotating drum machine, the availability of the twin coil artificial kidney enabled the spread of dialysis to many new centers. Interest increased because during the Korean war dialysis had proved invaluable in the management of military personnel with traumatic acute renal failure (10).

Blood Access and the Development of Chronic Maintenance Dialysis

Originally, hemodialysis required multiple arterial and venous cut-downs, one of each for each dialysis. Alwall attempted to obviate this by the use of siliconized glass tubes which were joined together between dialysis treatments by a narrow glass capillary (20). Heparin was injected into the tubing, but this approach was abandoned because of frequent clotting and local infection (21). The era of modern dialysis stems from development of the teflon arteriovenous shunt by Scribner and co-workers in Seattle (22), the first of which was implanted in March 1960. Two cannulae, made from thin-walled teflon tubing with tapered ends, were inserted into the radial artery and cephalic vein near the wrist and bent through a 180° turn before passing through the skin. Between dialyses the

external ends were connected to a curved teflon bypass tube using two Swagelock couplings fixed on a stainless steel arm plate. Because the rigidity of the teflon tubing caused mechanical damage to the vessel walls, this shunt was modified when flexible silastic tubing became available (23), and eventually a silastic shunt system with a single break joined by a single short teflon connector and with teflon vessel tips was developed (24). This, the "Scribner shunt," and its various modifications became widely used throughout the world during the 1960's (25).

At the same time as the development of the shunt, Scribner and his colleagues developed a new dialysis system for use with patients with chronic renal failure. This originally evolved from a system to treat acute renal failure with continuous low-flow dialysis using a low resistance dialyzer to make a blood pump unnecessary and a large volume of dialysis fluid which was cooled in order to minimize bacterial proliferation. Originally a Skeggs-Leonard dialyzer was used, but in 1960 a device originally developed as a blood oxygenator began to be used for dialysis, the Kiil dialyzer (26,27). The Kiil dialyzer was modified to reduce its blood volume, and a different cellophane, Cuprophane, was used as the membrane. The first patient, Clyde Shields, started treatment in March 1960 and lived for 11 years on maintenance dialysis, dying in 1971, aged 50, from a myocardial infarction. Of the two other patients who started treatment at the same time, one is still alive 25 years later, having had a living-related donor transplant in 1968. As a result of the success of this new treatment for chronic renal failure,

the Seattle Artificial Kidney Center was developed as the first outpatient community dialysis center. This was the first dialysis unit to be situated outside a hospital and the first unit in which dialysis was carried out primarily by nurses and not by physicians (28).

Further modifications of the dialysis system were made in Seattle, including the use of a single pass dialysate circuit in order to improve efficiency and reduce bacterial counts. Efforts also led to automation of the fluid supply system based on development of a system using a concentrated solution of electrolytes and dextrose which was diluted with tap water by means of an accurate proportioning pump system. This concentrated dialysate required the substitution of acetate for bicarbonate to avoid precipitation (29). A central dialysis system based on proportioning was built in Seattle to treat 15 patients using dialysate concentrate diluted 1:34 (31). It was while these developments were occurring that the Seattle Artificial Kidney Center developed its committee to select patients for this expensive and unusual treatment (28,31).

Home Hemodialysis

The next step in reducing the cost of hemodialysis was to move it to the home. Apparently, the first home dialysis was carried out in Japan in 1961 (32), but home dialysis as we know it today was introduced in 1964 in Boston (33), London (34), and Seattle (35). Besides being less expensive, home dialysis was also found to be

better for many patients in terms of increasing independence and the opportunity for rehabilitation (36). The Seattle group developed a modification of the proportioning system which became the standard for single patient dialysis systems (34). This system included several monitors and alarms with the intention of making overnight dialysis in the home a safe procedure to be carried out by patient and family member.

The Arteriovenous Fistula

While the Scribner shunt had made maintenance dialysis possible, problems with clotting, infections, and the need to replace the shunt plagued most patients. This was resolved in 1966 with the development of a surgically created arteriovenous fistula by Brescia and colleagues (37) which rapidly became the standard form of access for hemodialysis. Following this, for patients whose own veins are not suitable for development of an arteriovenous fistula, various grafts have been developed (38,39,40), but it is still true to say in 1985 that the "native" arteriovenous fistula remains the gold standard of blood access. Consequently one of the most important measures in the management of patients with chronic renal failure before they require dialysis is preservation of the forearm vessels so these can be used for development of a fistula when required (41).

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The Square Meter-Hour and Middle Molecule Hypotheses

The Seattle group was also involved in the early development of intermittent peritoneal dialysis (see below). Quite early on, Scribner noted that patients treated by chronic peritoneal dialysis were often underdialyzed in terms of blood chemistry but nevertheless did not show evidence of peripheral neuropathy, or if this was present when they started dialysis it did not progress (42). He suggested that the peritoneal membrane was more permeable than cellulose membranes and that peritoneal dialysis removed more of substances with a higher molecular weight than did hemodialysis. This led to the suspicion that so-called "middle molecules" might play an important role in the toxicity of uremia, and the hypothesis that for a given membrane prevention of peripheral neuropathy depends on a minimum number of hours of dialysis per week rather than on maintenance of specific blood levels of urea and creatinine. This, the square meter-hour hypothesis (43,44) and its modification, the middle molecule hypothesis (45), suggested that inadequate removal of middle molecules (molecular weight between 300 and 2,000 daltons) may be the cause of complications such as peripheral neuropathy and pericarditis. Since removal of middle molecules through a conventional hemodialysis membrane is slow, the diffusion gradient remains high throughout the dialysis, unlike the situation with small molecules. Thus the net removal rate for middle molecules remains constant during a protracted dialysis, and net removal is proportional to the total hours per week of hemodialysis, unlike

small molecules which have flow-dependent removal that decreases with the decreasing plasma concentration as dialysis proceeds.

These hypotheses had a major effect on dialysis equipment and strategies, even though the isolation, identification and toxicology of middle molecules remains clouded in uncertainty (46). However, they led to shortening of dialysis schedules using larger surface area dialyzers or increased frequency of dialysis, usually with less total dialysis hours per week. With the development of hollow fiber dialyzers using cellophane, Cuprophan and other membranes, large surface area dialyzers have become widely used during the 1970's with shorter dialysis times. Scribner and his colleagues also noted the importance of residual renal function with a short dialysis schedule, and its contribution to the removal of middle molecules (47,48). Residual kidney function should be measured and taken into account in planning short dialysis schedules (49). Average dialysis time has decreased by more than 50% between 1968 and 1978 (50).

The Redy System

Hemodialysis generally uses a large volume of water which must be pretreated, and requires access to a water supply and a drain. This interferes with portability. Consequently, efforts have been made to reuse dialysis fluid, and Gordon et al (51,52) developed a system to continuously regenerate a small volume (5.5L) of dialysate using a multilayer disposable cartridge containing urease, zirconium resins, and activated carbon. This, the Redy system, has been

available for some 15 years, and is relatively portable and can be used by dialysis patients who wish to travel. This interesting approach to dialysis has not been as widely used as might have been anticipated because of the large amount of supplies and accessories that have to be carried, and because the equipment itself has some disadvantages (53).

Sequential Ultrafiltration

During hemodialysis fluid is removed by ultrafiltration, usually in present-day machines by application of a negative pressure to the dialysate compartment. During dialysis, episodes of hypotension, muscle cramps, and other symptoms are common, particularly when a large volume of fluid is removed during a short dialysis. Bergstrom et al (54) were the first to observe that rapid ultrafiltration was better tolerated when performed without simultaneous dialysis by applying negative pressure while the dialysate bypassed the dialyzer. This process, sequential ultrafiltration, allowed the removal of as much as 4L of fluid in an hour, and could be followed by dialysis without producing a significant adverse effect on blood pressure (55-57).

Bicarbonate vs. Acetate

As noted earlier, the development of a dialysate proportioning system required the use of sodium acetate rather than sodium bicarbonate in order to produce concentrated dialysis fluid (29). This

was necessary in order to prevent precipitation of calcium carbonate. In recent years it has become apparent that many patients with acute renal failure and some sick patients with chronic renal failure may accumulate acetate in the blood and tissues during rapid large surface area dialysis, leading to acetate toxicity with vascular instability and hypotension (58,59). Similar undesirable side effects occur in other chronic renal failure patients dialyzed with large surface area dialyzers, particularly those who metabolize acetate slowly (60). Not only is the rapid infusion of acetate and the inability to metabolize it quickly a problem, but simultaneous loss of bicarbonate occurs from the blood through the dialyzer. It has been shown that use of bicarbonate dialysate frequently will relieve these symptoms (61) and consequently bicarbonate dialysis is being used more widely, this despite the fact that the equipment is somewhat more complicated and the dialysis is slightly more expensive.

Dialyzer Reuse

Dialyzer reuse was first developed in 1964 by Shaldon et al who refrigerated twin coil dialyzers and their tubing sets, together with the contained blood, between dialyses (62). In 1967 Pollard et al in Seattle developed a technique for reuse of the Kiil dialyzer-- a flat plate, nondisposable dialyzer (63). This technique allowed patients to put together their dialyzer and reuse it for as many as six dialyses. After dialysis the dialyzer was rinsed, cleaned with bleach, and sterilized using formaldehyde. With availability of

cheap disposable dialyzers, dialyzer reuse continued to be practiced at only a small number of centers, but with reduction in federal funding dialyzer reuse has again become important.

Dialyzer reuse is a safe procedure when carried out properly (64) but has been perceived by some patients as a means by which facilities may make money, and so during the late 1970's there was a strong patient movement against dialyzer reuse in the United States. This continues, but nevertheless more than 60% of patients in this country now are treated with reused dialyzers.

2. Peritoneal Dialysis

Peritoneal lavage was first described by the Reverend Steven Hales in 1744 (65), but it was not until 1877 that Wegner perfused the abdominal cavity of rabbits with a cold saline solution and observed a decrease in temperature (66). He went on to note an increase in the volume when concentrated sugar solutions or glycerol were placed in the abdominal cavity. A number of other studies on changes in outflow volume with solutions of different concentrations were reported over the next 40 years, but it was not until 1918 that the ability of the peritoneum to absorb fluid was first used clinically to treat children with gastrointestinal problems that prevented oral intake (67). Throughout the 1920's and 1930's studies were made on the diffusion of substances across the peritoneal membrane and the effect on blood levels, the mechanism for the increased outflow volume using hypertonic glucose, and the effect of vasodilatation and vasoconstriction on diffusion (68).

The first use of peritoneal dialysis to remove uremic toxins was by Ganter in 1923 in animals made uremic by ureteric ligation (68). He was also the first to report the use of peritoneal dialysis in the human, studying the effects of a physiological saline solution introduced intraperitoneally in a patient with ureteral obstruction due to uterine carcinoma, noting that her clinical condition showed slight improvement. Peritoneal dialysis was used clinically in a few patients during the 1930's, but the next major step was the publication of a report on the use of peritoneal dialysis in acute renal failure by Fine et al in 1946 (69). By 1950 there were reports on more than 101 patients treated by either intermittent or continuous peritoneal dialysis (70), and in the next 10 years peritoneal dialysis was used more widely for treatment of acute renal failure in adults and children, and to treat hypercalcemia and various poisonings.

Early Peritoneal Access Devices

Peritoneal access, originally achieved by means of a trochar and cannula, was a problem for repeated peritoneal dialysis. In the early 1960's there was intensive study of methods for repeated access, and various indwelling "buttons" and other devices were developed. Leakage and obstruction were serious problems, and generally these devices were not successful because of flow problems and lack of a closed dialysis system. However, in 1965 Weston and Roberts improved upon the Maxwell catheter by inserting a pointed

stylet (71). This became commercially available as the Trocath and it simplified access for temporary peritoneal dialysis considerably. However, access continued to be a major problem for patients on long-term peritoneal dialysis until the description by Palmer of a permanently implanted silastic catheter with a long subcutaneous tract (72). Working from this concept, Tenckhoff in Seattle attached dacron felt cuffs to the catheter just below the skin and immediately outside the peritoneum. Tissue ingrowth into these cuffs fixed the catheter in place and provided an effective barrier against bacterial invasion of the sinus tract around the catheter. This, the Tenckhoff catheter (73), originally implanted using a special trochar, has become the standard access device for long-term peritoneal dialysis, and a modification with a single cuff is widely used with acute renal failure.

Developments in Chronic Peritoneal Dialysis

The modern era of peritoneal dialysis was ushered in by publication of the monograph by Boen in the Netherlands in 1959. This classic work, published in the United States in 1964 (74), describes studies on the kinetics of peritoneal dialysis and discusses the indications, techniques, and complications of this treatment. This, together with the report by Maxwell et al from the United States (75), established the use of peritoneal dialysis in the treatment of acute renal failure. Because of its simplicity and because hemodialysis was not widely available at this time, peritoneal dialysis became widely used for acute renal failure.

In 1962 Scribner invited Boen to the University of Washington, Seattle, to continue his work on peritoneal dialysis and extend its application to the treatment of chronic renal failure. Equipment previously used for the experimental treatment of chronic renal failure by gastrodialysis was modified to make the first closed-system peritoneal dialysis cyclor using dialysate sterilized in 40L glass bottles (76). This closed system dramatically reduced the frequency of peritonitis because it eliminated repeated connections to fresh dialysate containers during the course of the dialysis (77). In 1963 Boen started treatment of a 28-year-old woman with chronic renal failure by outpatient intermittent peritoneal dialysis (IPD), and this continued successfully for four years until the patient was transferred to home hemodialysis. This patient is alive today, having had a successful related donor transplant in 1971.

Boen and Tenckhoff continued work on development of peritoneal dialysis equipment which would eliminate the need for large containers of sterile fluid and on equipment for home IPD. The first such equipment, using heat sterilization, became available in 1970 (78) but was bulky and heavy, and while successfully used by a small number of patients, was never a commercial success.

The early 1970's showed increasing interest in IPD for chronic renal failure, primarily as a result of the continuing work of Tenckhoff, supported by the National Institutes of Health. He next developed a peritoneal dialysis fluid supply system using a reverse osmosis device to produce sterile pyrogen-free water. It was this

equipment which made long-term IPD feasible (79). In the late 1970's there was renewed interest in the use of pharmacologic agents to improve peritoneal clearance and so reduce the long duration of a peritoneal dialysis, and the possibility of using dialysate regeneration also was explored (80,81). However, IPD was still used for less than 5% of patients in the United States, in part because of lingering suspicions based on the high infection rate associated with the use of open peritoneal dialysis systems in the 1960's.

The most notable advance in peritoneal dialysis in the 1970's was the brilliant conception by Popovich, a biomedical engineer who had previously worked on hemodialysis kinetics at the University of Washington in Seattle, of the principle of continuous ambulatory peritoneal dialysis (CAPD) (82). This technique of portable self-dialysis has undergone an astonishingly rapid increase in use worldwide (83) and now accounts for about 13% of dialysis patients in the United States (84).

The recent increased interest in peritoneal dialysis has also led to the development of another approach. In 1979 Scribner first proposed nightly automated peritoneal dialysis, together with daytime ambulatory peritoneal dialysis (85). This concept was developed by Diaz-Buxo and co-workers and has become known as continuous cycling peritoneal dialysis (CCPD). It may prove a very useful further form of treatment (86).

The Enhancement of Peritoneal Dialysis Efficiency

Various pharmacological and physiological factors may affect peritoneal dialysis efficiency, but most of these have been studied in experimental animals and have not made a significant contribution to the management of patients. Peritoneal dialysis is inherently inefficient, and peritoneal mass transport can also be altered by both peritonitis and by generalized vascular diseases such as diabetes or scleroderma which affect the splanchnic blood vessels. A major factor affecting the rate of transport is the concentration gradient, but for larger molecular weight substances which diffuse slowly, increasing the rate of exchange beyond about 2L an hour has little effect on clearance. To improve mass transport requires either increasing peritoneal permeability or surface area, or increasing blood flow.

Blood flow to the peritoneal membrane is primarily related to mesenteric blood flow rate, since the visceral peritoneum is much greater in area than the parietal peritoneum. Thus factors which affect the splanchnic vascular bed can affect blood flow. Pharmacologic manipulations can produce vasoconstriction and vasodilatation of the vascular bed, and in particular vasoconstriction can be prevented by use of the alpha receptor blocking agent phenoxybenzamine. Prostaglandins have also shown to be involved in the control of vascular dynamics, again by modification of vasoconstrictor responses (87).

Convective transport can also be improved by increasing the osmotic activity of the dialysate or increasing capillary hydrostatic pressure by causing greater constriction of venules than of the arterioles, as with dopamine (88).

A number of vasodilator agents have been tested. For example, isoproterenol at a concentration of 0.06mg/L in the dialysate does improve peritoneal transport, although the effect is transient (89). No systemic effects were noted at this dosage. Isoproterenol inhibits catecholamine response and relaxes the mesenteric vascular bed. Theophylline (90) and nitroprusside (91) have also been used. Dipyridamole is interesting as it increases peritoneal transport and can be given orally. It is a smooth muscle relaxant and also has an antiplatelet aggregating effect which may be helpful with systemic diseases that produce platelet thrombi in the mesenteric circulation (92). Other substance that have been used include dopamine (93), hydralazine (89), diazoxide (94) and tolazoline (95).

Prostaglandins alter regional blood flow by their effect on vasoconstrictor responses (87), but studies of prostaglandin synthetase stimulators and inhibitors have not shown significant changes in peritoneal transport (96). Various vasodilator gastrointestinal hormones have also been investigated, and in experimental animals both glucagon and secretin can increase mesenteric blood flow (97). It has also been shown that methylprednisolone increases peritoneal clearance significantly (98).

From the foregoing, it is obvious that a number of drugs and hormones affect the peritoneal membrane and splanchnic blood flow, but to this date these have not proved applicable to clinical practice. Further knowledge of the effects of drugs and their interactions may eventually enable enhancement of peritoneal transport.

3. Other Technologies

Hemoperfusion

In 1948 Muirhead and Reid found that urea was absorbed from animal blood by passing this through an exchange column, so initiating the principle of using sorbents for blood purification (99). Yatzidas then described attempts to treat uremia by perfusing heparinized blood through a column of activated charcoal (100). However, while activated charcoal is an effective sorbent for several potential uremic toxins such as creatinine and uric acid, it does not absorb urea or correct the water and electrolyte abnormalities associated with chronic renal failure. In addition, it soon became obvious that the charcoal had to be coated or microencapsulated to prevent particles from entering the bloodstream (101).

Hemoperfusion using coated activated charcoal or Amberlite resin presently is used as treatment for severe overdosage with several hypnotic drugs including barbiturates, glutethamide, chlorpromazine, and methaqualone (102-104). It has also been used experimentally as an adjunct to dialysis treatment for chronic renal failure (105-107) but does not appear to be a complete alternative

to either hemodialysis or peritoneal dialysis. In addition, hemo-perfusion with coated charcoal has been used to treat hepatic failure, but with inconsistent results (108,109).

Hemofiltration

Hemofiltration was introduced by Henderson and co-workers in 1967 (110), although the concept was originally described by Brull in 1928 (111). It has the advantage that it removes solutes by diffusion, as with conventional dialysis, and also by convection--a process which more clearly resembles the performance of the human kidney. Small and large molecules are removed at a similar rate. Introduction of the middle molecule hypothesis in the early 1970's stimulated work with hemofiltration, and a number of clinical trials have been undertaken (112-115). Different filters with different membranes can be used, including polysulfone, polyacrylonitrile, and asymmetric cellulose acetate membranes. Rather a large volume of fluid has to be ultrafiltered (20-40L 3 times weekly depending on body size), and an approximately equal amount of replacement fluid has to be added to the system either before (predilution mode) (116) or after the filter (postdilution mode) (113), and this replacement is one disadvantage of this treatment. The use of sorbent regeneration and reinfusion of ultrafiltrate has also been attempted and may be a feasible alternative (117).

Hemofiltration is an effective method to replace renal function, but removal of small molecules is somewhat less efficient than

with hemodialysis, and some loss of protein through the membrane of the ultrafilter has been described (118). On the other hand, better control of hypertension, improvement in peripheral nerve function, and other advantages have been reported (119). Nevertheless, for the present time, hemofiltration is expensive and rather cumbersome.

Hemodiafiltration

Hemodiafiltration is a combination of hemodialysis and hemofiltration which uses both diffusion and convection. It allows use of a shorter dialysis time, together with a smaller volume of replacement fluid than with hemofiltration (120). Intradialytic morbidity is said to be reduced, and small molecular weight clearances enhanced (121).

Plasma Exchange

Plasmapheresis was originally suggested by Abel and colleagues in 1914 "for the relief of toxemia" (3). Plasma exchange became feasible in the late 1960's and early 1970's with developments in the technology of working with extracorporeal circulation. Consideration has been given to the use of plasma exchange to treat a number of very different diseases, several of them being thought to have an autoimmune pathogenesis (122,123):

Two methods of plasma exchange are available--one of these is continuous flow separation--plasma separation, and the more recent

one is membrane plasma separation--plasmapheresis, which has become the treatment of choice since the availability of suitable membranes (124,125). Vascular access is usually by means of an arteriovenous shunt or subclavian catheter. During treatment, 4-5L of plasma are removed and replaced by fresh frozen plasma, reconstituted dried plasma, or an albumin electrolyte mixture (122,123). Treatment is usually carried out daily or on alternate days.

Other techniques are being developed such as use of two hollow fiber filters with different pore sizes. The first separates plasma from whole blood and the second separates filtrate from larger molecular weight substances. This filtrate is then mixed with the cell-rich residual blood from the first filter and returned to the patient (126). Other developments include selective plasma component removal (127) and plasma exchange with immuno-adsorption (128).

Plasma exchange is frequently combined with immunosuppressive therapy for the treatment of acute hypersensitivity glomerular diseases such as Goodpasture's syndrome and rapidly progressive glomerulonephritis. It has also been used for autoimmune and other diseases including thrombotic thrombocytopenic purpura, systemic lupus erythematosus, myasthenia gravis, Guillain-Barré syndrome, rheumatoid arthritis, scleroderma, and Raynaud's syndrome. Success has been variable, and treatment of these conditions requires further evaluation.

4. Important Medical Issues

Viral Hepatitis

About 1965 it was first recognized that hepatitis was a hazard in dialysis units, and in the next few years a number of serious outbreaks occurred in several centers in Europe and the United States. Both patients and staff were affected, and a number of deaths occurred (129,130). At the same time, considerable research was being carried out on viral hepatitis, and it was soon realized that after hepatitis B infection, persistent Australia antigenemia (HBsAg) could occur. Such individuals are potentially infectious to others, endangering both other patients and staff. As recently as 1984, in Europe there were 2,174 new cases of hepatitis in dialysis patients, of which most were due to hepatitis B (131). There were 360 cases in dialysis staff with one death, a significant improvement over 1980 when there were 566 staff cases and 11 deaths. Recommendations were developed in both the United States and Europe to help to control the spread of hepatitis in dialysis units, including isolation of affected patients, encouragement of home dialysis, and use of hyperimmune gamma globulin for protection following needle stick injury. Development of a successful vaccine for hepatitis B is now beginning to have a significant impact on the rate of infection for staff (132). Vaccination should be considered for all staff working in dialysis units who do not have antibodies to hepatitis B, and can also be used to protect patients, also, although it may be less effective in hemodialysis patients (133).

Other varieties of hepatitis also occur in dialysis patients. Hepatitis A may result from transmission from acute cases but does not pose a long-term hazard in dialysis units. However, with the introduction of reliable serological tests for hepatitis B infection, it soon became obvious that apart from a small number of cases due to cytomegalovirus, Epstein-Bar virus and drugs, there was yet another cause of hepatitis in dialysis patients. This, non-A, non-B hepatitis, results from an agent which is transmissible from man to chimpanzees (134), and for which a new antigen-antibody system has been distinguished (135). Like hepatitis B, non-A, non-B hepatitis infection does result in the carrier state and consequently can be a source of hepatitis in dialysis units. Unfortunately, non-A, non-B hepatitis is much more likely to result in chronic liver disease than is hepatitis B (136). Specific serological tests towards a specific non-A, non-B antigen called hepatitis C antigen are being developed.

In addition, a further hepatitis agent named "delta" has also been identified which is invariably associated with progressive liver injury in human carriers. This agent has an obligatory association with hepatitis B virus and cannot replicate without the latter's presence. So far, delta agent has not become a major problem in dialysis units, but is more commonly described in intravenous drug abusers (137).

Thus, while hepatitis B should be screened for on a regular basis in dialysis units and should no longer be a serious problem

with the availability of the vaccine, occasional brief outbreaks of hepatitis A may occur, and non-A, non-B hepatitis is appearing as a serious problem for some patients.

Anemia

Chronic renal failure is almost always associated with anemia, except in the case of a small number of the patients with polycystic kidney disease. The major cause for this anemia is the reduced production of erythropoietin by the kidney causing a reduction in red cell production (138). Several other mechanisms may be involved, including shortened red cell survival (139), toxic depression of erythroid proliferation and heme synthesis by uremic inhibitors (140,141), and blood loss occurring to a variable degree in association with the dialysis procedure (142). Anemia remains one of the major factors in the lack of well-being of dialysis patients and is important in preventing rehabilitation of such patients.

Institution of thrice-weekly dialysis in good time and a dietary protein intake of 1 to 1.5/g/kg/body weight/day helps to produce a higher hematocrit level in patients starting dialysis (143). Transfusions, because of their potential erythropoietic suppressive effect and the risk of transmitting hepatitis, should be given only when there is clear evidence of tissue hypoxia such as angina or where required as part of a transplant program. The serum ferritin level should be monitored regularly to check for development of iron deficiency, but unless there are unusually great

blood losses the patient who starts dialysis with normal iron stores takes six months to two years to develop iron deficiency. Once this occurs, it should be treated with oral iron taken before or after a meal, and without concomitant ingestion of phosphate-binding gels (144). For patients who cannot tolerate oral iron or in whom it does not produce improvement, parenteral iron-dextran can be used. However, this carries the risk of occasional systemic reactions (145) and the danger of producing iron overload. Dietary supplementation with folic acid and histidine should also be considered (146). In patients with refractory anemia, androgens may be of help but are associated with side effects (147). In addition, peritoneal dialysis, and in particular, CAPD, has been said to be associated with higher hematocrit levels.

Perhaps the most exciting recent development is the availability for investigation of human erythropoietin produced from recombinant DNA. If, as is hoped, this will produce a marked improvement in the anemia of patients with renal failure, this could be one of the most significant steps in improving the well-being of patients and increasing their activity and opportunity for rehabilitation (138).

Aluminum Toxicity

In 1972 a new clinical syndrome was described in a number of patients who had hemodialyzed in Denver, Colorado, for several years. This consisted of dyspraxia, speech abnormalities, myclonus,

seizures, personality changes, and an abnormal electroencephalogram, and progressed to death within a few months. All patients had been dialyzed with untreated Denver city water. Analysis of brain tissue for trace elements showed few differences from that of controls and of uremic patients who had died without signs of encephalopathy except for some reduction in the amount of rubidium and potassium and an increase in the content of tin (148). Aluminum was not estimated at that time. By 1976, 19 cases had been observed in Denver, and suspicion had been raised that aluminum was responsible as tissue studies showed brain aluminum to be four times higher than in dialysis patients who died from other causes and ten times higher than in nondialyzed patients, the aluminum being localized in the gray matter. Aluminum concentrations in muscle and bone were also higher than in controls (149).

At the same time, similar cases were being reported in England and in Canada from cities with a high aluminum content in tap water, frequently as a result of an aluminum precipitation method used to reduce any undesired color in the water (150). Further studies showed that dialysis encephalopathy had a geographical distribution which appeared to be related to the aluminum content of untreated or inadequately treated water used for preparing dialysate. More recently other symptoms associated with aluminum toxicity have been described including vitamin D-resistant osteomalacia, proximal muscle weakness (151), and a hypochromic microcytic anemia (152).

The kinetics of aluminum in dialysis patients are complex. Aluminum is bound to plasma protein, and uptake from dialysate may continue even when the total plasma aluminum concentration exceeds that in the dialysate. Transfer is also related to pH and is increased by increasing the pH of the water or by use of bicarbonate dialysate (153). A pH below 6.5 has a similar effect.

The other major source of aluminum which has become of increasing concern recently is the aluminum-containing phosphate binders which are routinely administered to dialysis patient to control phosphate intake (154,155). Efficient aluminum-free, and preferably magnesium-free, phosphate binders are currently under investigation.

Recently, the administration of desferrioxamine during dialysis has been shown to help remove aluminum from the body (156). Even so, because of the serious dangers associated with aluminum intoxication, it is important that water be pretreated by reverse osmosis or other means for all dialysis patients. Routine monitoring of serum aluminum levels should also be considered.

Osteodystrophy

Renal osteodystrophy, previously seen primarily as renal rickets in children, became a serious problem with the availability of maintenance dialysis. The association of hyperparathyroidism with renal disease has been known for some time (157), and calcium malabsorption has been found in such patients and is resistant to vitamin D treatment (158). However, it was found that renal

osteodystrophy can also be improved with large doses of vitamin D or dihydrotachysterol, that vitamin D increases bone resorption and there is a long delay between giving intravenous vitamin D and its physiological effects. Thus the interactions between the kidneys, the parathyroids, bone skeleton, and vitamin D are complicated (159).

DeLuca and his colleagues eventually showed that vitamin D had to be hydroxylated before it is physiologically effective (160), and the lag period can be shortened by giving 25-hydroxyvitamin D₃ which is also active in bone cultures. The 25-hydroxylation occurs in the liver microsomes and is a biofeedback-regulated process. However, 25-hydroxyvitamin D still did not appear to be the active agent. The next step was the finding that the kidney is a unique source of a potent hormone which stimulates intestinal calcium absorption and calcium resorption from bone. This was isolated and found to be 1,25-dihydroxyvitamin D₃ (161).

As a result of these findings, treatment of renal osteodystrophy and other disorders with synthetic vitamin D metabolites and analogues is possible. However, while vitamin D and its analogues have been shown to be effective in treating renal osteodystrophy, the osteomalacia in dialysis patients does not always respond to this treatment, and as noted above, aluminum accumulation may be the prime cause of osteomalacia in some of these patients.

There is no doubt that this better understanding of the interrelationships between vitamin D and its metabolites, the kidneys, bones, and alimentary tract has been a major advance in the management of patients with end-stage renal disease.

Lipid Abnormalities

In 1974 Scribner and co-workers reported the high morbidity and mortality from atherosclerotic cardiovascular disease in long-term dialysis patients in Seattle (162). Similar data has been reported by the European Dialysis and Transplant Association (163), and it now appears that cerebrovascular and cardiovascular causes account for approximately 60% of deaths in dialysis patients. Plasma lipid abnormalities have been shown to occur in dialysis patients, including persistent hypertriglyceridemia associated with a delay of the peripheral catabolism of very low density lipoproteins, and impaired triglyceride removal from a defect in lipoprotein lipase, presumably associated with the accumulation of uremic toxins (164,165).

Hypertriglyceridemia also may be increased by the use of dextrose in the dialysate (166) and also by use of acetate dialysate (167).

The major problem affecting long-term survival in dialysis patients is cardiovascular disease, and in addition to the lipid abnormalities described, the occurrence of hypertension appears to be a major factor. This underlines the importance of blood pressure control in all dialysis patients and also in patients with renal disease.

B. DESCRIPTION OF PRESENT-DAY PROCEDURES

1. Hemodialysis

Hemodialysis requires access to the bloodstream, a hemodialyzer, equipment to provide dialysate to the hemodialyzer, monitoring devices and alarms, treated water for preparation of the dialysate, and staff to carry out the treatment.

Hemodialyzers

More than 250 different dialyzers are available, of which about two-thirds are hollow fiber dialyzers and the remainder are parallel plate dialyzers. Coil dialyzers, which were very important in the past, are now used only infrequently.

The Membrane

There are three basic types of membrane used in dialyzers: cellulose acetate and cellulose-derived materials, Cuprophane, and membranes of synthetic materials such as polycarbonate, polyacrylonitrile, and polymethylmethacrylate. The type of membrane determines various characteristics of the dialyzer such as its thrombogenicity, its activation of complement, and the occurrence of allergic reactions during dialysis.

Dialyzers vary in their membrane surface area from 0.3m^2 to 2.5m^2 , and they also vary in the thickness of the membrane. The latter determines the clearance and ultrafiltration characteristics of the dialyzer and normally ranges from 8 microns to 40 microns.

Blood volume in the dialyzer ranges from 25-185ml and is relatively fixed in a hollow fiber dialyzer, but in a flat plate dialyzer is influenced by transmembrane pressure. Clearance rates of most dialyzers are in the range of 55ml/min to 180ml/min creatinine clearance, and the ultrafiltration rate (UFR) usually ranges from 0.5ml/hr/mmHg to 10ml/hr/mmHg. Newer high flux dialyzers are becoming available which have an even higher UFR. Thus there is a very wide range of dialyzers available with different physical characteristics, and a physician has a great deal of choice in picking the most appropriate one for the individual patient. This may be particularly important for dialysis of the patient with acute renal failure who is extremely sick, for other unstable patients, and for pediatric patients. Excellent summaries and tabulations of the various dialyzers are available (168,169).

Hemodialysis is most often carried out three times weekly, the duration of dialysis generally being in the range of 3 to 5 hours, although the effects of even shorter dialysis times are being studied (170). Three-times-weekly dialysis is a compromise between the increase in the time taken to prepare and to clean up after dialysis and the advantages to be gained from more frequent dialysis. Empirical experience has shown that for most patients three times weekly is the optimum. Some patients elect to dialyze more frequently; others, particularly those who may have significant residual renal function, may dialyze only twice weekly.

Dialysis is a remarkably safe procedure, and it has been estimated that the death rate from technical or human error is only about 1 in 75,000 dialyses (171). This is equivalent to one death every 480 years for dialysis 3 times weekly. There are several problems which can occur with dialysis. Blood leaks due to imperfections in the membrane are extremely rare, as are blood leaks related to human error. However, other problems that may occur with dialyzers include anaphylactic and allergic reactions during dialysis (172,173). These may relate to inadequate removal of sterilants from the dialyzer before use, the leaching of substances from the potting material in hollow fiber dialyzers, or allergic reactions to the membrane itself. Most reactions have occurred with Cuprophane membranes; they have been less common with dialyzers using regenerated cellulose or other cellulosic membranes, and affected patients do not react to synthetic membranes such as polyacrylonitrile. Probably the most important single cause of an allergic reaction is the presence of residual ethylene oxide, and ethylene oxide-related sensitization has been found in a proportion of hemodialysis patients but not in patients treated only by peritoneal dialysis (174). In addition, in many of the patients who experience an acute allergic reaction it is possible to demonstrate the presence of IgE against human serum albumin exposed to ethylene oxide (175). Unfortunately, ethylene oxide cannot be completely removed by the usual rinsing process, but changes in the manufacturing process are already

occurring because the rate of severe hypersensitivity reactions has declined since 1982 when it was 3.5 reactions per 100,000 hollow fiber dialyzers sold (176).

Dialysate and the Dialysate Supply System

Currently, most dialysis equipment uses dialysate prepared from a concentrate which is diluted with treated water and which is then delivered to the artificial kidney. Usually, the dialysate is then discarded to the drain--single pass dialysis. The concentrate is diluted 1:34 with water, and the concentrate most commonly used includes acetate rather than bicarbonate as anion because this allows concentrate preparation without precipitation of calcium salts (29). Generally, dilution is performed in a proportioning unit which is part of the dialysis equipment. Bicarbonate dialysate has also been used with greater frequency recently, even though it requires somewhat more complex equipment and is more expensive.

The dialysis equipment also includes various monitors required in order to make the procedure relatively safe, and in fact, single patient dialysis equipment was developed in Seattle in order to make overnight hemodialysis a safe procedure for patients to carry out at home. Typical monitors include a monitor of pressure in the blood circuit, a blood leak detector, a temperature monitor, a negative pressure monitor which permits estimation of transmembrane pressure and may directly allow measurement of ultrafiltration, and an air detector to prevent the occurrence of air embolism with breaks in the extracorporeal circuit (177). Appropriate alarms are connected

to the monitors and can be set to specific limits. Typically the equipment includes a blood pump as, while pumpless dialysis can be done with cannulas and a low resistance system, the pressure in an arteriovenous fistula is generally insufficient and a blood pump is required to achieve an adequate blood flow rate. In addition, the equipment includes a heparin pump to maintain anticoagulation of the patient throughout dialysis.

Dialysate composition, adjusted according to the choice of the physician and the needs of the individual patient, is generally such as to match normal blood electrolyte levels or to induce changes in the patient's blood levels to more closely approach normality. Generally, the dialysate sodium concentration is set between 136-147mEq/L. This is somewhat higher than in the early years of dialysis because it has been found that use of a higher dialysate sodium concentration is associated with less dialysis morbidity, presumably related to prevention of a sudden fall in plasma osmolality with dialysis (178,179). The problem with using a high dialysate sodium content is that this may increase thirst and consequently produce greater weight gain and may result in hypertension and pulmonary edema between dialyses (180). Most patients tolerate a sodium concentration of 135mEq/L, and only in the minority is a higher or lower sodium concentration required to control problems during dialysis. Generally, if the sodium concentration of acetate dialysate has to be increased, this should be done by addition of sodium bicarbonate.

The dialysate potassium concentration is generally 2.0mEq/L, but the patient's serum potassium should be monitored and the dialysate concentration altered as needed. Patients with pre-dialysis potassium levels of greater than 6.0mEq/L usually need a lower potassium concentration in the dialysate. Contrarywise, acutely ill patients, those with severe acidosis, those receiving parenteral glucose and/or bicarbonate, and particularly those using a digitalis preparation, may require a higher dialysate potassium concentration to prevent the occurrence of cardiac arrhythmias during dialysis associated with a rapid reduction in serum potassium level (181).

The calcium content of dialysate is adjusted in order to result in a slight net flux of calcium into the patient during dialysis so as to help to counter the calcium deficiency which occurs in patients with chronic renal failure. The recommended dialysate calcium concentration is between 3 and 3.5 mEq/L. Patients dialyzed against a lower level than this frequently develop secondary hyperparathyroidism and increasing renal osteodystrophy, whereas a higher level than 3.5mEq/L results in hypercalcemia (182).

The recommended dialysate magnesium concentration is between 0.5 and 1.0mEq/L. Higher levels may result in hypermagnesemia which can result in abnormal mineralization, and magnesium-free dialysate can result in magnesium deficiency (183).

Glucose was used in dialysate originally in order to enhance fluid removal during treatment, also providing extra calories and

reducing symptoms. However, the usual dialysate glucose concentration of 200mg% appears to have little impact on the quality of dialysis, and as glucose is one of the more costly constituents of dialysate its use is probably not required.

The buffer base in dialysate is used to correct the metabolic acidosis and bicarbonate deficiency which occurs in uremic patients, and to replace bicarbonate which diffuses from blood to dialysate if bicarbonate is absent in the dialysate. Because calcium and magnesium bicarbonate are relatively insoluble, particularly at higher pH levels and in concentrated solutions, acetate was substituted for bicarbonate when dialysate concentrate was first developed for proportioning systems (29). Acetate is a physiological buffer which is metabolized to bicarbonate in the body. In a relatively inefficient dialysis, acetate dialysate creates no problem because acetate is presented to the body at a rate which was easily metabolized. With development of large surface area dialyzers the rate of acetate influx and bicarbonate loss increased, and many patients develop clinical symptoms such as headache, vomiting, nausea, cramps, and hypotension (184). Symptoms appear to relate to an increase in organic acid and acetate levels in the blood, and comparison of infusion of acetate and of other organic acids has shown that hypoxemia and decreased serum potassium, phosphate and glucose levels occur only with acetate infusion (185). Acetate has also been shown to cause myocardial depression and vasodilatation (186, may affect lipid synthesis (187), and is more likely to cause hemodynamic instability and symptoms during dialysis (184).

Bicarbonate dialysate may also have long-term benefits. Patients on acetate dialysis generally have a lower predialysis bicarbonate level and this chronic acidosis may be harmful to bone mineralization. Aluminum complexes are less dialyzable in the pH range 7-7.4, and more rigid pH control with bicarbonate may help to reduce the influx of aluminum from dialysate to blood (153). The effect of long-term bicarbonate dialysis on the lipid profiles is still disputed, but several studies have shown that growth hormone release may be suppressed by acetate (188,189). It has also been suggested that plasma ketone levels may increase with increase of plasma acetate levels, suggesting hormonal variations facilitating fatty acid oxidation during acetate dialysis (190). On the other hand, bicarbonate dialysate is relatively unstable, is more expensive, and is nonbacteriostatic, although recently use of a stabilizer has been reported to deal with this problem.

Water

The water used for preparation of dialysate is usually tap water from the local supply, and as such, likely contaminants include particulate matter, bacteriological contaminants, and chemical contaminants.

Particulate matter does not cross the dialysis membrane but may obstruct conduits in the dialysate supply system, and so an appropriate filter in the water line is required to protect the system from damage.

The dialysis membrane also acts as a barrier to both bacterial and pyrogenic materials, and so dialysate does not need to be pyrogen-free or completely sterile. However, a major membrane leak with unsterile dialysate may result in septicemia, although small leaks are not usually a cause for concern.

Pyrogenic reactions may result from use of water for dialysate with a high bacterial count because of endotoxins passing the membrane, but not all febrile reactions are related to bacterial contamination. Nevertheless, bacterial growth in the dialysate and water supply system should be controlled. Methods have included the use of filters, ultraviolet light exposure, reverse osmosis, use of safe and nondialyzable disinfectants, and various combinations of these methods. Periodic culture of the water supply and of dialysate as it leaves the dialyzer is recommended. A colony count in the water of greater than 200 colonies/ml, and in the postdialyzer dialysate of greater than 2,000 colonies/ml, should trigger search for a source of contamination.

Various chemical contaminants may be present in water, and suggested maximum levels for these have been set based on EPA standards for drinking water (191). Use of appropriate water treatment equipment should prevent many of the hazards associated with chemicals, but in dialysis centers which do not use water treatment the possibility of chemical contamination of the water should be monitored regularly.

Water treatment devices include water softeners, cellular filters, reverse osmosis devices, and deionizers. Water softeners are the least expensive but are less reliable and serve to reduce calcium, magnesium, iron, and manganese levels. They are particularly useful in areas with hard water but have a limited spectrum activity--sodium is exchanged for cations, and fluoride and other toxic substances may not be removed.

The most effective means of chemical purification include deionization, reverse osmosis, and distillation, choice depending on demand and the type of contamination. Deionizers are effective against most chemical contaminants, while reverse osmosis is good for bacteriological, organic, and pyrogenic contamination. Generally, with small demand situations deionizers are more suitable, while for larger installations reverse osmosis, with or without one or more deionizers, has proved better. Charcoal filters are also valuable for removal of chloramines, dimethylnitrosamines, and pyrogens. Distillation requires a bulky apparatus, is energy-inefficient and expensive, and is rarely used.

Technique of Dialysis

During hemodialysis, movement of solutes and water occurs along the concentration gradients. The process of diffusion from an area of higher concentration to one of lower concentration is a net transfer of mass as a result of random thermal movement. However, the dialyzer also has another type of transfer, the process of ultrafiltration of plasma water along with those solutes of small

enough molecular size to cross the membrane--this is called convective transport. The latter is independent of the concentration gradient and depends chiefly on the mechanical pressure difference between the two sides of the membrane. Both diffusive and convective processes occur during conventional hemodialysis.

Diffusion of a solute depends mainly on molecular size rather than permeability of the membrane. As the size of the molecule increases, the net mass transfer decreases. Thus smaller molecular weight solutes are rapidly removed by dialysis and removal rate is influenced by blood and dialysate flow rates. In contrast, larger molecular weight substances are removed less efficiently, and the rate of removal is not influenced by blood or dialysate flow rates, but rather by duration of the dialysis procedure.

2. Peritoneal Dialysis (192)

Peritoneal dialysis is dependent upon access to the peritoneal cavity without undue risk of bacterial contamination and the development of peritonitis. For patients with chronic renal failure a permanent indwelling silastic catheter is the only practical method for long-term treatment, and the usual catheter is the Tenckhoff catheter (73). As described previously, this has one, or more commonly two, dacron felt cuffs, the inner of which is placed immediately outside the peritoneum, and the outer of which is located just below the skin exit. The catheter is inserted either at the bedside using a trochar and cannula or may be inserted surgically.

Once in place the catheter must be kept clean and dry, and before and after each dialysis the catheter exit site should be cleaned with betadine or hydrogen peroxide. Careful attention must be paid to connection and disconnection from the catheter during peritoneal dialysis.

Various other peritoneal dialysis catheters have been devised, the one most commonly used at the present time being the Toronto Western Hospital catheter (193).

Complications associated with placement of indwelling peritoneal dialysis catheters include leakage of dialysis fluid, bleeding, reflex ileus and, rarely, bowel perforation.

There are a number of long-term complications associated with peritoneal catheters including skin exit infection, most commonly due to staphylococcus aureus or epidermidis. Tunnel infections also occur and may extend deep into the abdominal wall and can be a cause of repeated episodes of peritonitis. Catheter cuff erosion and prolapse may occur due to pressure and necrosis of the skin at the exit site. This requires elective catheter replacement.

Catheter malfunction often presents as a failure to drain the peritoneal cavity at the start of dialysis, and outflow obstruction is much more common than inflow obstruction. Common causes include involvement of the catheter in adhesions, catheter malposition, catheter entanglement in the omentum and catheter obstruction by incarceration of tissue. Dye injection and X ray is often helpful in elucidating the problem. Catheter revision may be required.

Failure to drain also frequently occurs as part of a functional problem and responds to bowel stimulation by an enema. This treatment should always be tried first before looking for a mechanical cause of catheter failure.

The Peritoneal Membrane

The peritoneal membrane has a surface area of between 1 and 2m². Solute removal occurs by diffusion from the blood in the peritoneal capillaries to the dialyzing solution infused into the peritoneal space (194). Solutes with molecular weights of up to 30,000 daltons may cross the peritoneal membranes. Solute removal depends on dialysate flow rate, temperature, pH, and osmolality. Fluid removal with peritoneal dialysis is carried out by osmosis, using a dialysate of higher dextrose content. Dextrose is poorly absorbed across the peritoneal membrane and therefore creates an osmotic gradient for fluid removal (195).

Intermittent Peritoneal Dialysis (IPD)

Intermittent peritoneal dialysis generally is performed using a machine to deliver sterile dialysate to the peritoneal cavity. After a suitable dwell time, the machine may pump the fluid out or siphonage may be used. Spent dialysate can be collected in a container or may be delivered to a floor drain. The simplest piece of equipment is a cyclor which operates by gravity or a pump and feeds a fixed volume of sterile peritoneal dialysate stored in several

large bags through an octopus head of tubing, through a heater chamber, and into the patient's peritoneal cavity for a preset dwell time. The peritoneal cavity is then drained automatically and the cycle repeated (196). The second type of equipment used for IPD, which unfortunately is no longer manufactured, depends on reverse osmosis to prepare sterile, pyrogen-free water which is then mixed with sterile concentrate by a proportioning pump in order to produce sterile peritoneal dialysate (79). The dialysate is then pumped into the peritoneal cavity and timers are used to preset the duration of inflow, dwell time, and outflow. While reverse osmosis equipment is more complex and more expensive than a cyclor, the supplies required for each dialysis are much less expensive because the dialysate is prepared in the machine and less plastic tubing is used. Treatment is usually carried for 10-12 hours overnight, 3 nights weekly. While peritonitis does occur, this should be less than one episode per 2 years.

The main problem with IPD is the eventual occurrence of underdialysis as the patient's residual renal function declines, so requiring either longer dialysis time than many patients find convenient or more frequent dialysis. In addition, the mortality rate appears to be greater with IPD than with long-term hemodialysis (197), although this may be more a question of patient selection.

Continuous Ambulatory Peritoneal Dialysis

Continuous ambulatory peritoneal dialysis (CAPD) is a form of home peritoneal dialysis in which the patient dialyzes continuously

by infusing 2 liters of sterile dialysate from a flexible plastic bag into the peritoneal cavity (193). The bag is then rolled and carried in a pocket or belt during a dwell time of 4 to 6 hours or overnight. During the dwell time the patient can be active and carry on most normal activities. At the end of the dwell time the dialysate is drained into the empty bag. This is then detached and replaced by a fresh bag which is used in turn to refill the peritoneal cavity. This process of drainage, disconnection, connection, and infusion takes 30 to 45 minutes. New techniques which allow disconnection from the bag during dwell time are being evaluated. Various techniques and equipment for connection and disconnection are available, but so far none has been shown to be superior to normal connection and disconnection. CAPD is simple to carry out, does not require the assistance of a second person, allows the patient greater mobility, does not require use of a machine, and is well tolerated by many patients. Its major problems are its continuous nature, 7 days weekly, from which the patient has little or no respite, and the risk of the occurrence of peritonitis which occurs an average of slightly more than one episode per year (199). Repeated episodes of peritonitis may lead to technique failure due to reduced efficiency of dialysis, and it is then necessary to transfer the patient to hemodialysis.

Continuous Cycling Peritoneal Dialysis

Continuous cycling peritoneal dialysis (CCPD) is a combination of IPD and CAPD in which the patient uses a machine (either a cycler or reverse osmosis equipment) for peritoneal dialysis overnight while sleeping (196). Prior to disconnection in the morning, 2 liters of fresh dialysate are instilled into the peritoneal cavity, and this remains in place until connection for the next dialysis that evening. This technique reduces the number of connections as compared with CAPD and so may lessen the risk of peritonitis. It also avoids the need and inconvenience of making bag changes during the day. However, it requires nightly IPD for 8 hours or more to provide adequate dialysis.

Complications of peritoneal dialysis

The complications associated with peritoneal dialysis include mechanical problems, infections and peritonitis, metabolic effects, cardiovascular and pulmonary problems.

Mechanical complications include the occurrence of pain in the rectum or bladder area due to malposition of the catheter. In addition, pain in the shoulder may be referred from the diaphragm and associated with abdominal distention with air or excess dialysate. Bleeding may occur into the peritoneal cavity, but despite appearances this is usually not a serious problem. Leakage of dialysate may occur around the catheter, and subcutaneous dissection with dialysate can occur when one of the catheter holes is outside the

peritoneal cavity, or with leakage through the peritoneal membrane into the muscles and subcutaneous tissues. The most serious mechanical complication is bowel perforation, and the risk of this can be minimized by careful attention to detail during insertion of the peritoneal catheter.

Peritonitis remains the single most important complication with all forms of peritoneal dialysis. The incidence rate varies from facility to facility, but with IPD should be less than one episode per two years of treatment. The latest United States data on CAPD shows an infection rate of slightly more than one episode per year of treatment, and this has been slowly improving for several years (199). Bacteria can gain entry into the peritoneal cavity through the lumen of the catheter or by way of the catheter tract, and meticulous sterile technique during connection and disconnection is essential. Peritonitis usually presents with fever, abdominal pain, tenderness, discomfort, and/or a cloudy peritoneal fluid on outflow. A specimen of fluid should be sent for gram stain, cell count and culture, and appropriate antibiotic therapy started. Many episodes of peritonitis can be treated at home by suitably trained patients and without admission to hospital. Infection may also occur along the catheter tract, and this requires meticulous local care and the use of systemic antibiotics. Catheter replacement may be required with resistant or repeated episodes of catheter tract infections.

Infection with hepatitis B virus can also be a problem for peritoneal dialysis patients. Such patients should be vaccinated

against this and should be tested routinely for hepatitis B because of the risk associated with the presence of high concentrations of virus in the peritoneal fluid. Whether a similar risk applies to patients who have antibodies to HTLV-III or who have acquired immune deficiency syndrome remains to be determined.

Metabolic problems associated with peritoneal dialysis include protein loss, which may be as much as 9 to 10g of protein daily. However, most patients eating a diet containing 1.2g of protein/kg body weight/day probably will not have problems with this. A second common problem is hyperglycemia and hyperlipidemia associated with absorption of glucose from the dialysate.

The pulmonary complications of peritoneal dialysis include pneumonia and atelectasis as a result of abdominal distention and limited respiratory movements. With marked abdominal distention, the volume of the exchange can be reduced to provide relief. Pleural effusion, when it occurs, is usually right-sided, presumably due to dialysate passing through a defect in the diaphragm. Cardiovascular problems can also occur, particularly in patients with preexisting cardiac problems who become either severely overdistended or severely volume depleted.

3. Sequential Ultrafiltration

Sequential ultrafiltration is the separation in time of the ultrafiltration process and diffusion dialysis (54-57). This may be particularly helpful in patients with hemodynamic instability.

During ultrafiltration, as fluid is removed cardiac output and stroke volume decrease but systemic vascular resistance increases, and as a result, blood pressure remains stable. This is in contrast to the diffusion dialysis process which, if associated with ultrafiltration, results in a reduction in cardiac output and stroke volume associated either with a decrease or with no change in systemic vascular resistance, so resulting in hypotension. Thus isolated ultrafiltration permits easier removal of a larger volume of fluid at a faster rate without the development of hemodynamic symptoms. Hemodynamic stability during ultrafiltration may relate to the fact that proteins are not removed during ultrafiltration, so that the plasma oncotic pressure rises, with consequent refilling of the plasma space and maintenance of blood pressure. In contrast, in diffusion dialysis, as the osmotic pressure of extracellular fluid declines, fluid moves into the cells and extracellular fluid volume is lost to both dialysate and the intracellular space, resulting in a fall in blood pressure. A combination of initial ultrafiltration followed by diffusion dialysis, so-called sequential ultrafiltration, is helpful in many patients with hemodynamic instability.

Complications of ultrafiltration include worsening of the metabolic acidosis, possibly due to movement of intracellular fluid into the extracellular space, thus lowering bicarbonate concentration; loss of bicarbonate with ultrafiltration (200); and development of lactic acidosis (201). Hyperkalemia has also been reported, perhaps related to movement of intracellular fluid into the extracellular space and the associated metabolic acidosis. Hypotension

may occur if the ultrafiltration rate exceeds 0.5ml/min/kg body weight. In the long term, sequential ultrafiltration may lead to hypercalcemia and hyperphosphatemia, together with an increased parathyroid hormone level and a decline in nutritional status in some patients (202).

Hemofiltration

This is the process of ultrafiltration with associated removal of uremic toxins by the convective process, and has some resemblance to glomerular filtration. Hemofiltration depends on use of a relatively porous membrane to carry out the ultrafiltration, and equipment to provide a carefully metered volume of fluid to replace the plasma that has been ultrafiltered (110). Originally called diafiltration, hemofiltration differs from ultrafiltration in that the ultrafiltered fluid is replaced by an electrolyte solution similar in composition to plasma.

The restraint offered by the membrane to passage of a solute is measured by the sieving coefficient. This is the ratio of the concentrations of solute on the filtrate side and the blood side of the membrane. A solute which passes freely across the membrane will have a similar concentration on both sides of the membrane and a sieving coefficient of one. On the other hand, a solute which does not pass the membrane at all will have a sieving coefficient of zero. Different solutes have sieving coefficients between these two values (203). Small molecules such as urea and creatinine pass

freely through a regular dialysis membrane, and if the concentration gradient is favorable, large quantities will be cleared by diffusion. In contrast, larger molecules will not be cleared as readily and their clearance is negatively correlated with the size of the molecule. With convective clearance, clearance is largely size-independent and is dependent on solvent drag of water moving through the membrane under a pressure gradient resulting in bulk movement carrying solutes with it in about the same concentration as plasma. Thus for solutes which pass the membrane clearance is approximately equal to the volume of water filtered in unit time. Other factors which influence the transport of solutes are the Gibbs-Donnan effect of protein and the effect of ionic charge. The viscosity of the blood, related to hematocrit and protein concentration, can also affect passage of solute through the membrane.

The technique of hemofiltration requires passage of blood from the patient through a hemofilter where ultrafiltration of plasma occurs as a result of a pressure gradient. This can be generated either by increasing pressure on the blood side or reducing pressure on the ultrafiltrate side. Replacement fluid containing glucose and electrolytes in similar concentrations to plasma is infused either before the blood enters the hemofilter (predilution) or after the blood leaves the hemofilter (postdilution). Predilution hemofiltration is believed to result in better clearance of solutes (116), while postdilution is less expensive and more convenient as it uses a smaller volume of replacement fluid (113). A combination of these

two techniques can be used. The size of the equipment is related to the need for accurate replacement of fluid, and an automated system which removes and replaces 20-120L of fluid in 4 hours has to be technically complex to avoid the risk of an imbalance between the volume removed and that replaced. In addition, unlike dialysate for hemodialysis, the replacement fluid must be sterile and pyrogen-free. The cost and complexity of the equipment is one of the major reasons why hemofiltration has not gained more popularity in the United States. Its advantages are the increased clearance of large molecular weight substances, the occurrence of less morbidity during dialysis, and better tolerance of the procedure.

Hemodiafiltration

Hemodiafiltration is a combination of hemodialysis and hemofiltration in order to obtain the advantages of both (120,121). Thus it relies on both diffusion and convection. Hemodiafiltration requires a smaller volume of replacement fluid, and allows the shortening of dialysis time by as much as 40% without signs or symptoms of underdialysis. At the same time, small molecular weight clearances are enhanced, including phosphate clearance, and intra-dialytic morbidity is reduced. Investigation of the role of this treatment is continuing.

Continuous Arteriovenous Hemofiltration

Recently continuous arteriovenous hemofiltration using a small hemofilter and without a blood pump has been used in some patients

with acute renal failure requiring dialysis (204). Initial results have been encouraging, and this technique is worthy of further evaluation.

4. Dialyzer Reuse

Dialyzer storage and reuse was first attempted in 1964 using anticoagulation and refrigeration of twin coil dialyzers, the attached blood tubing sets and the contained blood (62). In 1967 a reuse technique was developed in Seattle to save home dialysis patients the time and trouble of rebuilding the nondisposable Kief dialyzer for each dialysis (63). A similar technique was developed for disposable flat plate dialyzers and hollow fiber dialyzers when these were first introduced, primarily to reduce the cost before the enactment of the Medicare ESRD Program in 1973. However, following 1973, with the relatively generous reimbursement for outpatient hemodialysis, there was little incentive to reuse dialyzers.

In recent years dialyzer reuse has become much more widespread in an attempt to contain the cost of dialysis, but there has also been considerable concern on the part of some patients regarding both the short- and long-term safety of reused dialyzers. Two major studies have concluded that dialyzer reuse is safe, efficacious, and not associated with any increased rate of complications (64,205). Many patients in Seattle have reused each of their dialyzers 6 or more times for 5 years or more without adverse effects. Apart from the economic considerations, a reprocessed dialyzer also carries a

lesser risk of causing allergic reactions, is associated with a lesser degree of leukopenia during dialysis, and is generally better tolerated (206). In recent years automated equipment has been developed for cleaning and disinfection of dialyzers, and this equipment can also check dialyzer functions such as fiber bundle volume and ultrafiltration rate.

The use of formaldehyde as the disinfecting agent for reuse of dialyzers has been one major cause of concern. Recently, the Center for Disease Control has recommended use of a 4% formaldehyde solution for dialyzer reprocessing because of seasonal variation in the risk of bacterial contamination with relatively resistant organisms such as the mycobacterium species. Use of 4% formaldehyde solution requires a larger volume of rinsing fluid to remove formaldehyde from the dialyzer, and testing is necessary to insure that there has been complete removal prior to connection to the patient. Four percent formaldehyde is an unpleasant substance to work with, and spills require special handling. Development of antinuclear-like antibodies may occur as a response to residual formaldehyde reaching the patient, and these antibodies have been implicated as a cause of hemolysis in some dialysis patients (207). Because of these and other problems, new disinfectants such as Alcide are being examined as possible replacements for formaldehyde.

Another concern with reuse is the possibility of inadequate dialysis, either because of diminished effective membrane surface

area or because of alterations to the membrane itself. However, most studies have shown that ultrafiltration and clearance of small molecular weight substances are not impaired with reuse.

A number of substances are available to clean the membrane for dialyzer reuse before it is disinfected. Hypochlorite bleach, reverse ultrafiltration, water flush, hydrogen peroxide, peracetic acid and sodium hydroxide have all been used. While bleach is widely used, some membranes deteriorate with this; and in addition, cleaning may be so complete that bleach-cleaned dialyzers may behave like new dialyzers in producing the first-use syndrome and are more likely to be associated with significant complement activation.

C. DIALYSIS SETTINGS AND PRESENT-DAY PRACTICE IN THE UNITED STATES

1. Acute Renal Failure

Acute renal failure is most commonly caused by acute tubular necrosis, generally following ischemia, and is most often associated with cardiovascular or hepato-biliary surgery, traumatic injury, sepsis or pancreatitis. Consequently, almost all patients with acute renal failure are hospitalized because of the underlying cause and associated complications, and treatment is by in-hospital dialysis.

Generally it is preferable to use single patient dialysis machines for this purpose rather than to have a separate area set aside for dialysis of patients with acute renal failure. Sicker patients require dialysis in the intensive care unit, but with appropriate plumbing and electrical connections it is possible to dialyze other patients who are less sick in a regular hospital room. Generally, the equipment is the same as that used for patients with chronic renal failure, including the use of water treatment as may be necessary.

2. Chronic Renal Failure

The dialysis of patients with chronic renal failure can be done in a hospital, in a freestanding dialysis unit, or at home. The nomenclature is somewhat confusing.

Hospital Dialysis

A hospital may perform two forms of dialysis: inpatient dialysis for hospitalized patients who suffer from chronic renal failure, and outpatient dialysis for outpatients with chronic renal failure.

Inpatient dialysis for hospitalized patients with chronic renal failure is often managed in the same way as described previously for hospitalized patients with acute renal failure. However, in smaller hospitals which have an outpatient dialysis unit, patients with acute renal failure may be treated in the dialysis unit. This is not necessarily in the best interests of the patient and staff because the patient with acute renal failure may require much closer surveillance than the outpatient with chronic renal failure. Also, it may be disturbing to stable patients with chronic renal failure to be treated in proximity to a patient with acute renal failure and multiple complications. Thus, wherever possible, inpatient dialysis should be provided either in the intensive care unit or in the individual patient's room. Only the stable patient with chronic renal failure who is an inpatient for a condition such as minor elective surgery and who has relatively little in the way of complications should be treated in a hospital outpatient dialysis unit.

Hospitals also may provide outpatient dialysis for patients with chronic renal failure. The Medicare ESRD Program divides institutions that provide outpatient dialysis for chronic renal failure into two categories: dialysis centers which are hospital

units that also provide all the usual services provided by hospitals, and dialysis facilities which are outpatient, freestanding dialysis units (see below) which contract with a hospital to provide in-hospital services for their patients. There are 662 hospitals out of a total of 1,368 institutions approved to provide chronic dialysis services in the United States (208). In Europe, in contrast, until recently at least, the majority of outpatient dialysis was carried out in hospital units. This can create confusion in comparing European and American statistics, as in Europe "hospital dialysis" for chronic renal failure generally means outpatient dialysis.

The major advantage of a hospital dialysis unit is that it uses the existing administrative structure of the hospital, but the disadvantage is the higher overhead and other costs associated with hospital services. Also, there is evidence that hospital units may treat a sicker patient population than outpatient dialysis units.

Out-of-Hospital Dialysis

As noted above, more than half the institutions providing outpatient dialysis in the United States are "out of hospital," and these are categorized by the Medicare ESRD Program as dialysis facilities. They have also been called freestanding, limited care or out-of-hospital dialysis facilities. It is only recently that such facilities have been developed in Europe.

Typically, an out-of-hospital dialysis facility provides staff-assisted outpatient dialysis and, like a hospital dialysis unit, can

provide all modalities of treatment other than inpatient dialysis. Freestanding units may be associated with hospitals or may be independent. They may be nonprofit institutions or may be for-profit and, in the latter case, may be owned by individuals or by a corporate chain. One such entity, National Medical Care, currently dialyzes about one quarter of the patients in the United States.

Self-Care Dialysis

In the early 1960's it was realized that one of the major factors contributing to the cost of dialysis was personnel. By training the patient and family or other helper to perform dialysis at home the cost could be reduced significantly. This requires a specific home dialysis training program, and both hospital and freestanding dialysis units may have such a program. Patients may be trained for home dialysis, or more recently, some patients have been trained to do self-care dialysis in the dialysis unit.

Home dialysis involves the patient and a family member, or in some programs a paid dialysis helper when a family member is not available, in order to assist the patient to do their dialysis at home (209). While originally developed because of its cost-saving potential, home dialysis was soon found to have other advantages, and in particular, increasing patient independence, freedom, and opportunity for rehabilitation (210). Self-care dialysis in a dialysis unit has also been used for similar reasons, usually in a

situation where a number of patients dialyze themselves, perhaps with the assistance of family members, and with minimal assistance from the staff.

Self-care dialysis, whether in the home or in a unit, requires an organized patient training program. Training should begin as soon as possible after the patient is started on dialysis so that independence can be encouraged. The staff providing training should be selected for their teaching abilities as well as their knowledge of dialysis, and training should, if possible, be carried out in an area separate from that used for regular maintenance dialysis. The training program should include information about kidney disease and its complications, blood access, diet, medications, and the various procedures for the form of self-dialysis selected by the patient. Training may be on a one-on-one basis or may be in groups. Written materials, slides, posters, and videotape programs have all been used to assist with training. Training for home IPD and for CAPD and CCPD is of shorter duration than for home hemodialysis. Generally, peritoneal dialysis training takes one to two weeks, and hemodialysis training takes from three weeks to three months. Patient progress needs to be assessed during training, and it is important that as far as possible the patient be made responsible for their own care in order to avoid becoming overly dependent on the spouse or other helper. The availability of a paid home dialysis helper permits some patients to be trained for home dialysis who do not have a family member or whose family member is not

willing to undertake this (209). Successful home dialysis requires a careful initial assessment of patient and family and the availability of good social work follow-up.

Self-care dialysis requires blood access that is easy to use, and most patients can be taught to insert their own needles into a suitable arteriovenous fistula or graft. The dialyzer used, duration of dialysis, and ultrafiltration rate should be selected individually for the patient so as to minimize the occurrence of symptoms during dialysis. Similarly, hypotensive drugs should be used with care in self-care dialysis patients. Dialysis equipment and water treatment should be chosen because of reliability, ease of use, adequacy of monitoring, and availability of repair service and maintenance support.

Home dialysis requires well organized follow-up services. Generally, the patient is reviewed monthly in the physician's office and can mail in ahead a monthly predialysis blood sample for analysis, reports being sent to the physician, the training program, and the patient. Records should be kept of each dialysis and forwarded to the training program. Arrangements must be made for provision of supplies and for maintenance and repair of equipment. Ongoing social work support, vocational rehabilitation services, and nutritional advice are also important. In addition to being able to contact the physician, a home dialysis patient should at all times have ready access to a nurse from the training program who can advise as to what services are required in the event of a problem or emergency.

Selection of Patients for Various Modalities of Dialysis

This is discussed in a further section.

D. MANPOWER NEEDS

Little has been published on the manpower needs associated with dialysis in different settings (211,212). Thus this section will consist of general comments on manpower requirements for direct patient care and those for supporting and administrative services.

1. Acute Renal Failure

Patients with acute renal failure are hospitalized, and in many cases will be sick enough to require treatment in an intensive care setting.

Nephrologists and other physicians

Because acute renal failure usually occurs as a complication of another condition, many of these patients will have an attending physician who is not a nephrologist. Nevertheless, dialysis of patients with acute renal failure should always be supervised by a nephrologist. With the availability of dialysis equipment in many hospitals and the growth of outside services which will provide dialysis equipment and dialysis nurses to hospitals which do not possess these, dialysis for acute renal failure is being carried out in many hospitals which do not have a chronic dialysis program. Nevertheless, with the large number of nephrologists in the United

States, it should always be possible for a nephrologist to be involved in the care of a patient with acute renal failure.

Registered nurses

Dialysis for acute renal failure should always be carried out by an experienced registered nurse trained in provision of both hemodialysis and/or peritoneal dialysis in patients with acute renal failure. Where a facility does not have nurses trained in dialysis and is using dialysis services provided from elsewhere, the procedure should always be done by a suitably trained registered nurse provided by the outside agency.

Dialysis technicians

Because of the severity of the patient's illness, dialysis in patients with acute renal failure generally should not be done by a licensed practical nurse or a patient care technician. Equipment technicians will be required to maintain, service and repair the equipment, the number being dictated by the quantity of equipment available.

2. Chronic Renal Failure

Inpatient hospital dialysis

The patient with chronic renal failure who requires in-hospital dialysis has other medical problems, and so it is important that the dialysis be carried out by an experienced registered nurse. Because all patients with chronic renal failure should already be under the

care of a nephrologist, he or she should continue to be responsible for the patient's dialysis. Generally speaking, licensed practical nurses and patient care technicians should not do the dialysis of the hospitalized patient with chronic renal failure.

Outpatient hospital dialysis and limited care staff-assisted dialysis

Almost all ESRD patients are followed by a nephrologist who is responsible for their care. In addition, units providing outpatient dialysis, whether hospital-based or freestanding, should be under the supervision of a medical director who is a nephrologist, and who may or may not be the nephrologist caring for the individual patient.

As a general rule, outpatient dialysis should be under the supervision of a registered nurse trained in hemodialysis or peritoneal dialysis as the case may be. Nevertheless, the hands-on dialysis care can be given by registered nurses, licensed practical nurses, or patient care technicians, provided that all have had appropriate training. As a general rule, one staff member should be able to care for at least three dialysis patients. Because administration of drugs may be required during dialysis, it is generally advisable to have a registered nurse available, even if the dialyses are performed by patient care dialysis technicians. In some states, the law requires that a registered nurse be present to supervise dialysis in an outpatient unit. In situations where a large number of stable patients are being dialyzed, the patient-nurse ratio may be 4:1, 5:1 or greater, at the discretion of the unit. There are

also units which treat a large number of unstable patients with cardiovascular instability and other medical problems during dialysis. In these circumstances, one nurse may be required for each two patients on dialysis. However, this should not be necessary for the majority of dialysis patients.

Equipment technicians are required to maintain, service, and repair the dialysis equipment. No information is available on the number of machines that can be cared for by one technician, and there is a lack of good job definitions.

As a general rule, all the staff involved in the care of the patient treated in an outpatient dialysis unit should be familiar with dialysis, should have been appropriately trained, and this training should be documented.

Self-care dialysis training

Self-care dialysis training is best provided by staff who are experienced in dialysis and who are chosen for their abilities to teach patients, to allow them to learn by making mistakes, and to encourage independence. These qualities are difficult to define, but training staff need to be selected carefully if a self-care dialysis training program is to be successful.

Self-care dialysis in a dialysis unit

Patients trained to perform their own dialysis require relatively little assistance and supervision during dialysis. Consequently, one staff member can manage five, and perhaps as many as

ten, patients carrying out self-dialysis. Such an individual need not necessarily be a registered nurse, but could be a suitably trained licensed practical nurse or patient care technician. However, as a general rule, it is still preferable to have an experienced registered nurse available on the premises.

Home dialysis

Home dialysis generally requires the presence of a second person during dialysis, with the exception of continuous ambulatory peritoneal dialysis. Generally, a patient should be trained to carry out their own dialysis, utilizing a family member or a paid dialysis helper to provide a second pair of hands and to assist the patient in carrying out the dialysis. Such family members or dialysis aides need to be trained in the same way that the home dialysis patient is trained. Occasionally, very independent patients may feel they can carry out their own home hemodialysis or home IPD without the assistance of a second person. In the case of home hemodialysis, this is particularly inadvisable as fatalities have occurred, usually associated with a blood leak or bleeding, when the patient has become unconscious and unable to resolve the problem. Consequently, no home hemodialysis patient should dialyze without a second individual readily available who knows enough to be able to discontinue dialysis and who is trained to handle likely emergencies. In the case of home IPD and CCPD, this may not be necessary as the problems that occur related to the dialysis are unlikely to be so

acute as to render the patient unable to help themselves. CAPD by its very nature is a procedure that the patient carries out themselves during their daily activities, and there is no need for the assistance of a family member or paid helper. The only exception is in the case of infants and very small children treated by CAPD or CCPD. The latter treatment may be preferable in such children because CAPD, with its need for frequent changes, becomes a major time commitment for the mother or other family member involved.

Supporting and administrative staff

Supporting and administrative staff are required for patients dialyzing as outpatients, and for patients dialyzing at home. Again, no good information is available as to how many patients can be supported by one such individual.

Nurses

For successful home hemodialysis, it is important that patients have good supporting services from the home dialysis training program or from the dialysis unit following the patient. A nurse should be available 24 hours daily on call by telephone and pager in order to answer the patient's questions during dialysis, to discuss problems, and to make the decision as to whether the patient requires to speak to their physician, whether they should continue the dialysis, whether the patient should be referred to other individuals or services such as a social worker, equipment repair

technician, etc. One nurse can provide on-call support for a large number of patients, and at the Northwest Kidney Center one nurse is on call for more than 200 patients dialyzing at home. Similarly, patients treated by any form of peritoneal dialysis should have a nurse who can be contacted at any time to answer questions that may arise.

In addition, the training staff or other dialysis staff must be available to see home dialysis patients at the unit if there are questions to be answered or minor technical issues to be resolved. Generally this is not a major need for hemodialysis patients, but for CAPD patients a nurse is required for various services such as tubing changes, and one nurse can be responsible for the care of 10-20 such patients.

Equipment technicians

The equipment of the home dialysis patient must be maintained, serviced, and repaired. These services can be provided by equipment technicians from the manufacturer or supplier, or may be provided directly by the facility. Because the home dialysis patient is usually well dialyzed, there is no need to have a 24-hour repair service available. Arrangements should be such that an equipment problem in the home can be attended to promptly the following day so as to avoid the patient having to come to the unit for a backup dialysis. Patients should be taught the basic maintenance of their equipment, but the equipment service technician should provide routine major servicing, as well as responding to patient problems.

Suppliers

Home dialysis patients, whatever form of home dialysis they may be undertaking, require provision of an adequate quantity of supplies. In many cases, this function is delegated to the manufacturer or an outside supplier, but it behooves the facility to insure that appropriate supplies are ordered. Some facilities may provide supplies directly, allowing better inventory control, but otherwise inventory management and accounting should be coordinated between the unit and the supplier.

Social workers

Dialysis, whether as an outpatient or at home, puts stress on patient and family, and many readjustments are required at the time when a new patient first starts dialysis. At a later stage, patients and their families may develop problems requiring the services of a social worker. Medicare regulations require that all dialysis facilities have the services of a social worker, but no criteria have been laid down as to how many patients one social worker can follow. The social worker must be familiar with dialysis and the problems of dialysis patients. Generally, it is preferable for all new patients to be interviewed by a social worker prior to the start of dialysis, and during the early months of treatment a social worker should be available to provide advice and counseling, including advice on rehabilitation services and employment. Once the patient is established on dialysis social support must continue to be

available, but generally is not required to the same degree. In the Northwest Kidney Center program, one social worker is responsible for approximately 100 patients, including both center and home dialysis patients. Unfortunately, some facilities do not have a social worker who is closely involved in patient care, but rather have a part-time social worker who serves merely to meet the requirements of the Medicare regulations.

Financial counselors

Some facilities employ financial counselors who specialize in the finances of end-stage renal disease and who can establish the patient's financial responsibilities, the availability of various funding sources, and counsel the patient as to the best use of their resources. Such individuals can be invaluable to both patient and facility by insuring that patients take maximum advantage of the financial services available to them. As with social work support, financial counseling is particularly important at the time that a patient commences dialysis. It is also helpful if the patient's financial situation is reviewed on a regular basis in order to insure that the patient continues to make the best use of available resources.

Nutritionists

Diet is an important part of the management of patients with chronic renal failure, and recent evidence suggests that nutrition

may be important in delaying the onset of dialysis (213). Once a patient starts dialysis there is an ongoing need for nutritional services. New patients should spend time with a nutritionist, and a careful program of nutritional advice, support and regular review should be available for all dialysis patients. Generally, one nutritionist can support as many as 100 dialysis patients.

Administrative and other staff

In the case of a hospital, most of the administrative services required by the dialysis unit are provided through the hospital. Nevertheless, each unit, whether in a hospital or freestanding, must have a medical director who should be a nephrologist. Many free-standing units also have an administrator who is responsible for such services as billing and accounting, personnel functions, and the general supporting functions required in operating a dialysis unit. In some smaller units and in units that belong to larger organizations, much of the administrative services may be provided off-site by a central administration.

E. CURRENT EXPERIENCE WITH DIALYSIS

1. The Present-Day Patient Population

Patient demographic data from the the Health Care Financing Administration are shown in Tables 1 through 4. The changes in the patient population which ensued with passage of the Medicare ESRD legislation and subsequent general availability of dialysis and transplantation have been described (214). This paper examined the dialysis patient populations in 1967 and 1976, and showed the increase in the number of elderly patients, minorities, especially blacks, the less educated and the less well-to-do. These changes have continued. Most striking is the large percentage of patients aged 65 and older who are on dialysis. Such patients accounted for 25% of all dialysis patients in 1981 (215). There has also been a marked increase in the incidence of patients with diabetic end-stage renal disease, and this now accounts for more than 25% of new patients. These changes are important for two reasons. First, until recently patients over the age of 65 have not been considered as suitable candidates for kidney transplantation, although this may change with more experience with the use of cyclosporine. Second, the increase in the number of elderly patients and diabetic patients means that a much greater portion of the ESRD patient population is likely to have vascular and other complications which affect survival and also increase morbidity. The frequency of hospitalization is greater in these patients, with consequent financial impact on the cost of the Medicare ESRD Program. It is uncertain whether all the

patients with diabetic end-stage renal disease and all the elderly patients who might benefit from treatment are being referred. However, the proportion of elderly ESRD patients will continue to increase because of aging of the general population, and the dialysis population in the United States is not likely to stabilize before the year 2030 (216).

Transplantation is a factor which will affect the future number of patients on dialysis. Assuming an increased availability of cadaver kidneys, it is likely that in the future the great majority of younger patients will receive a kidney transplant. Although there will continue to be a significant failure rate for cadaver grafts, with the patients then returning to dialysis, and while some of these patients will have high levels of cytotoxic antibodies making retransplantation both less probable and less successful, nevertheless, the number of patients on dialysis aged 35 and under is likely to decline in the future (216). Consequently, the proportion of elderly patients on dialysis is likely to increase even further.

2. Selection of Treatment for the Individual Patient

Patient and physician have a number of options to select from in deciding which modality of treatment is best for the individual patient. While some general guidelines are available, there remains the problem that good comparative information on the best form of

treatment for the individual patient is sparse. Much of the survival information available does not take into account the effect of patient selection for different modalities of treatment.

Friedman has listed the important factors governing selection of treatment as patient age, cause of renal failure, physician bias, patient bias, economic realities, and the use of investigational treatments (217).

Patient age

Infants and children under the age of one generally do not do well with hemodialysis, and CAPD or CCPD, which reduce the time demands on the parents, may be the preferred forms of dialysis. Transplantation in very small children has been more successful with the use of adult living-related donors (218)¹, although short-term results with cadaver transplants are also said to be improving (219). In older children, hemodialysis, CAPD and CCPD are all effective forms of treatment, but in general home hemodialysis, CAPD or CCPD are to be preferred rather than outpatient dialysis in order to give the best opportunity for schooling and leisure activities. Unfortunately, growth tends to be subnormal in children on dialysis, but may improve following transplantation. Consequently, transplantation should be considered for all children, and it also offers the best opportunity to return to school and other activities (220).

As noted earlier, almost half the new patients starting treatment in the United States are aged 55 or older, and almost half the patients enrolled in the Medicare ESRD program are 55 or older. These numbers will continue to increase. Survival is less good than in younger patients, but nevertheless, the results of treatment with dialysis are such as to warrant treatment of patients at all ages. The question remaining to be answered is the role of transplantation in patients aged 55 to 70 now that cyclosporine is available. Prior to cyclosporine, this age group did not do well with transplantation, primarily because of lesser tolerance for steroids and their side effects. Now, if enough kidneys become available, more such patients may be transplanted.

Meanwhile, for patients over the age of 55 the best treatment probably is hemodialysis, and home dialysis is to be preferred when practical, but CAPD or CCPD are reasonable alternatives for some patients.

For patients in the age range from adolescence to late middle age--say 55 years--survival with both dialysis and transplantation is at its best. Nevertheless, assessment of comparative morbidity and mortality of patients in this age group is difficult because of the need to compare equivalent subpopulations in terms of age, sex, race, socioeconomic status, and diagnosis. Transplantation will depend on availability of a living-related donor or a cadaver kidney. Generally, transplantation should be encouraged, particularly in younger patients, in order to maximize independence and rehabilitation.

Where this is not available, home hemodialysis, CAPD or CCPD are preferable, but many patients will, by default, be treated by long-term outpatient hemodialysis.

Cause of Renal Failure

This is also important in considering treatment. Some diseases recur following transplantation, and so oxalosis, focal segmental glomerulosclerosis, and membranoproliferative glomerulonephritis may be relative contraindications to transplantation, and cancer, either primary or metastatic, is an indication for delaying or avoiding transplantation.

A significant number of patients who start dialysis may recover sufficient renal function to stop dialysis for a period of time. These include some of the patients with malignant hypertension, gouty nephropathy, renal cortical necrosis, and also patients with renal failure due to toxic nephropathy, especially in the elderly. Patients with renal failure due to these causes should be observed on dialysis for 6-12 months before transplantation is considered to give opportunity for any improvement in residual renal function.

For patients with serious cardiovascular problems, peritoneal dialysis may be the treatment of choice, and CAPD may be preferred for patients who want home dialysis but who do not have a partner. The overall role of CAPD remains uncertain. Enthusiasts argue that this should be the primary treatment for most patients today, but some are beginning to question the long-term use of CAPD because

the peritonitis rate is not improving, even after 7 years of experience (221). For selected patients CAPD is a very satisfactory form of treatment; but unfortunately, because of the relatively high rate of technique failure, only a minority of patients will be able to continue on CAPD for more than 3 years. Ideally, patients who can no longer be treated by CAPD should be encouraged to undertake home hemodialysis in order to maintain their independence, but this is not always possible. Peritoneal dialysis is in no way a contraindication to either living-related donor or cadaver donor transplantation.

Intermittent peritoneal dialysis (IPD), while relatively simple to undertake, is expensive, even when used at home, and as residual renal function declines patients may require prolonged hours of treatment making this unacceptable. Continuous cycling peritoneal dialysis (CCPD) may be a reasonable alternative, but its long-term value has not yet been established. Thus maintenance hemodialysis remains the usual mode of therapy for the majority of patients, particularly the elderly.

Physician Bias

Examination of data from around the world shows a wide variation in treatment distribution from country to country. In part, at least, these differences represent physician bias (222). For example, in Canada peritoneal dialysis is used to treat 35% of the dialysis patient population, whereas in the United States this is 15%. Home hemodialysis is widely used in Australia and Canada, to a

lesser extent in the United States and Britain, and yet in Japan it accounts for less than 1% of patients. The use of all forms of home dialysis varies widely in different parts of the United States, sometimes markedly in adjacent states; for example, the home dialysis rate in Indiana is much higher than in Illinois.

Individual physician biases also occur. Transplant surgeons generally favor this over dialysis, and some nephrologists favor home dialysis or CAPD much more than others (223).

Patient Bias

The patient should be actively involved in selection of their treatment, and they may ignore the best intentioned medical advice. Fear, anger and hostility may all affect patient behavior at the time when treatment is started. Many patients are not seen by a nephrologist until the time to start dialysis, and patients are influenced by the attitudes of the physicians they meet. Religious beliefs also may affect their decision. It is important that patients have access to as much relatively unbiased information as possible. One approach to this is a specific orientation program during the first two months of dialysis to give the patient a better understanding of the various options available to them (224).

Economic Situation

Treatment choices also may depend on economics. In western nations, politics and economics may influence use of various forms

of treatment, and this is illustrated by comparing the treatment of end-stage renal disease in the United States and the United Kingdom (225).

New Treatments

As of today, maintenance hemodialysis remains the standard against which other treatments must be judged, age for age and diagnosis for diagnosis, in terms of survival and morbidity. Nevertheless, hemodialysis is not ideal. The complications of uremia persist, renabilitation is often incomplete unless the patient is treated at home, and treatment remains expensive.

Hemofiltration and hemodiafiltration were used to treat 2,867 patients in 25 countries throughout Europe in 1983, as compared to 76,179 patients on hemodialysis (226). Comparable data is not available for the United States. The drop-out rate with hemofiltration is less than one third of that with CAPD (115), and patients managed first by hemodialysis appear to tolerate and even prefer hemofiltration because of fewer symptoms. However, long-term patient experience with hemofiltration is still minimal, and it remains an investigational procedure.

Conclusion

The choice of treatment for a uremic patient is still far from an objective exercise. Only with much more statistical information, and preferably with comparative trials of age- and diagnosis-matched

treatments, will physicians and patients be able to review the options objectively, reflect on the various pressures, and make an informed decision as to which treatment is best for the individual patient.

3. Major Complications

Table 5 illustrates the common causes of death in the dialysis population based on data from the Northwest Kidney Center. The major cause of death remains cardiovascular and cerebrovascular disease, and this may relate to both hypertension before and after starting on dialysis, and also to the lipid abnormalities which are common in these patients. Smoking has also shown to be a major adverse factor in mortality from cardiovascular disease in dialysis patients (227). With patients now surviving for 20 years or more following the start of dialysis, the importance of prevention of vascular disease is paramount. Also, apart from progression of the renal disease itself, the major cause of progression to renal failure in patients with primary kidney disease is poorly controlled hypertension (228), and the diseased kidney appears particularly prone to further damage from hypertension (229). Consequently, it is becoming obvious that control of hypertension is perhaps the single most important factor that can be manipulated to prevent progression to renal failure, and this is true whether or not dietary means can also slow the progression of renal disease.

The one change in causes of death that has occurred is the increase in the number of patients in whom dialysis is discontinued,

either at the patient's request or, in the case of incompetent patients, at the request of relatives. Recent data from Minneapolis (230) and on our experience at the Northwest Kidney Center is that about 10% of all deaths occur after cessation of treatment. Diabetics and elderly patients are the most likely to have dialysis discontinued because the quality of their life has deteriorated.

In a population which dies predominantly from complications of cardiovascular disease and hypertension, a significant proportion of the morbidity is also associated with cardiovascular disease. This accounts for 20% or more of the hospitalizations of patients with end-stage renal disease in our program.

Another major problem for patients with end-stage renal disease is the occurrence of complications related to blood access. The preferred mode of blood access is the native arteriovenous fistula (231), and where this is not available a number of other techniques are available, the most common being an arteriovenous graft of Gortex or a vein graft (232). As many patients have the potential to survive for long periods of time, circulatory access requires careful planning and great attention to detail. Problems with access often relate to events occurring long before the patient requires dialysis. Casual placement of indwelling intravenous catheters in forearm veins during an intercurrent illness can result in thrombosis and loss of veins so that it is not possible to establish a native arteriovenous fistula. It is therefore essential

that patients with early renal failure be aware that they should warn medical and nursing personnel not to use forearm veins for any purpose unless absolutely necessary.

A well-functioning, mature fistula can be used for many years; we have one patient who has now used the same arteriovenous fistula for 20 years. Access surgery, whether an arteriovenous fistula or a graft, should be performed only by vascular surgeons who devote a considerable part of their time to access surgery and who, with the nephrologist, can assume long-term responsibility for maintenance of satisfactory circulatory access to each patient (233).

The common problems with arteriovenous fistulas and grafts include thrombosis and infection. For thrombosis, percutaneous angioplasty, injection of urokinase or streptokinase, or thrombectomy may be used; and in patients who have a tendency to recurrent clotting, a small dose of aspirin or other antiplatelet agent may be helpful. Thrombosis occurring in a mature fistula is usually due either to a hypotensive episode or to pressure on the fistula during an unrelated procedure. Infection in fistulas is often related to needle punctures for dialysis and usually responds to antibiotics. In a small proportion of cases, aneurysmal dilatation of the fistula may occur but can usually be corrected surgically. Other complications include venous hypertension and ischemia of the hand, and occasionally cardiac and hemodynamic complications may be associated with the high blood flow through a fistula. Endothelial hyperplasia at the anastomosis sites and consequent thrombosis is

more common in arteriovenous grafts than with fistulas: transluminal angioplasty may be used to correct this problem.

Access surgery is uncomfortable, and if it has to be repeated frequently is discouraging to the patient. Consequently complications due to access should be minimized. Nevertheless, access problems remain one of the major reasons for hospitalization and for morbidity in dialysis patients, accounting for 15% of hospitalizations in our program.

F. SURVIVAL RESULTS WITH DIFFERENT MODALITIES OF TREATMENT

Over the years there have been a number of reports on survival of patients with end-stage renal disease with the various modalities of treatment. These have come from individual facilities and from national registries such as the European Dialysis and Transplant Registry (131), the Canadian Registry (234), and the Australian and New Zealand Registry (235). Unfortunately at this time, there is no comparable national ESRD registry in the United States. Consequently, in order to illustrate the effects of treatment, the following results, except when stated otherwise, relate to patients treated through the regional program based on the Northwest Kidney Center in Seattle. Over the years this program has treated more than 2,000 patients by the various modalities of dialysis and by transplantation (236).

What has been clearly demonstrated is that survival of patients with end-stage renal disease depends on a number of factors. Age at the time of starting treatment is one of the most significant of these. When survival curves are drawn based on ten-year age intervals, irrespective of the form of treatment, there is a smooth decrease in survival with increasing age, which suggests a linear relationship (Figure 1). Linear, quadratic, and cubic models have been developed, but neither the quadratic nor the cubic model give any significant improvement in fit over the linear model for describing the effect of age on survival. In our experience the only exception to this age relationship is in patients under the age of 15, and this presumably reflects the lesser survival in the youngest patients (those under the age of 5). Similar results have

been found by others (237). What should be noted is that for patients aged 65 and over, the 5-year survival, irrespective of treatment, is approximately 25%. There was no difference in survival between males and females.

When patient survival was studied by race, there appeared to be slightly better survival in "other" patients--primarily Asians and American Indians--than in blacks or whites, but this was not of statistical significance (Figure 2).

Another major factor affecting survival is the cause of the renal disease. This has been analyzed for the commoner causes of chronic renal failure--chronic glomerulonephritis, diabetic nephropathy, congenital renal disorders, polycystic kidney disease, pyelonephritis, and primary hypertensive disease (Figure 3). Patients with renal failure secondary to congenital disorders have somewhat better survival, presumably because of their younger age. Those with renal failure due to diabetic nephropathy or primary hypertensive disease showed significantly poorer survival, presumably related to their generalized vascular disease.

A further major factor affecting survival is the presence of pre-existing disease or diseases at the time of starting dialysis. Figures 4 through 7 illustrate the effect of the presence of severe hypertension, cerebrovascular disease, cancer, and coronary artery disease on survival. There are significant differences related to all these preexisting problems. Survival is also related to the number of preexisting associated diseases the patient has at the time of starting treatment, whether or not these are comparable in severity (Figure 8).

The other remaining major issue is whether survival is comparable in patients with the different modalities of treatment. Patient survival has been compared with related donor transplantation, cadaver donor transplantation, and hemodialysis (238). The patient population was subdivided into those with diabetes or primary hypertensive disease as the cause for their renal failure, and those with other causes. While the duration of survival was less in the diabetic and hypertensive patients, the results of comparison of the modalities of treatment were similar in both population subgroups. Related donor transplantation clearly had better patient survival than the other modalities of treatment, but patient survival with hemodialysis and cadaver transplantation was not significantly different when account was taken of the time spent on dialysis prior to transplantation, and of the differences in age, number of associated diseases, and year of treatment in the patient populations treated by the different modalities. This analysis used the Cox proportional hazards model (239).

This leaves unanswered the question of comparison of survival with the different forms of dialysis. Conventional wisdom is that home hemodialysis patients have a better survival than center hemodialysis patients, that survival with CAPD may or may not be similar to that with hemodialysis, and that survival with intermittent peritoneal dialysis may be inferior. However, again, the problem is the different patient populations selected for the various treatments, selection being based on both medical and nonmedical factors. Consequently, the results in the patient population treated in the Northwest Kidney Center program between 1975

and 1986 has been analyzed using the Cox proportional hazards model. Comparisons were made between the different modalities of dialysis and with cadaver transplantation. When known risk factors were taken into account, intermittent peritoneal dialysis was found to be significantly inferior in terms of survival in comparison with center hemodialysis, home hemodialysis and CAPD. Home hemodialysis survival was somewhat better than center hemodialysis, but not significantly so, and there was no significant difference in survival between home hemodialysis, CAPD, and cadaver transplantation. These analyses also confirmed the importance of age and number of associated diseases as factors affecting survival, and showed that patient educational level had no bearing on this. Again, the year of treatment affected survival, patients treated more recently having better results than patients treated in the early years of the last decade. Unfortunately, there were not sufficient patient numbers to examine survival with CCPD.

The importance of these results is the assistance they give in selection of treatment. Rather than survival, the decision as to the form of dialysis for a given patient should be based on an evaluation of differences in the complications associated with the various forms of dialysis, and the potential effects of these on the patient's lifestyle, opportunity for rehabilitation, and family and social responsibilities. These same considerations should apply in making the decision as to whether a dialysis patient should receive a cadaver transplant. In this regard, the various reports on quality of life studies with different modalities of treatment are of importance (240,241). It also is apparent

that intermittent peritoneal dialysis, at least three times a week IPD as practiced over the last ten years, is a form of treatment which results in inferior survival, presumably because of inadequate dialysis as suggested previously (197). Consequently, it becomes important to gather information on CCPD to see whether results with this may more closely resemble those with CAPD.

These findings also suggest that an integrated program providing all modalities of dialysis and transplantation gives the greatest opportunity for optimal treatment of patients with end-stage renal disease. Unfortunately, at this time there is not enough information to compare survival with transplantation and dialysis in patients over the age of 65, but presumably these will not differ significantly from those illustrated here from a population representing all ages of patients.

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000041

TABLE 1

Medicare ESRD Program incidence rates
per million population, by age, sex, and race:
1978-80

Age, sex, and race	1978	1979	1980	Percent change 1978-80
Total	71	78	82	15
AGE				
0-14 years	6	6	7	17
15-24 years	26	26	24	-3
25-34 years	53	54	58	9
35-44 years	35	34	36	1
45-54 years	120	135	136	13
55-64 years	173	193	204	18
65-74 years	208	230	241	15
75 years and over	96	134	153	59
SEX				
Male	32	90	95	16
Female	61	67	70	15
RACE				
White	59	63	67	15
Black	159	184	185	16
All other	118	131	140	19

Reprinted from HCFA Review 5:69, 1984.

000012

TABLE 2
Medicare ESRD program incidence rates per million population,
by age, sex, and race: 1978-80 average.

	Race								
	All Persons			White			All Other		
	Total	Male	Female	Total	Male	Female	Total	Male	Female
TOTAL	77	89	66	63	74	52	169	186	154
0- 4 years	3	3	2	3	4	3	2	3	2
5- 9 years	6	7	6	6	7	6	6	7	5
10-14 years	13	13	12	12	13	12	14	16	13
15-19 years	21	23	19	19	21	17	30	32	27
20-24 years	32	37	28	28	31	24	57	70	46
25-29 years	46	55	37	38	44	31	94	122	70
30-34 years	61	75	47	48	58	39	143	196	99
35-39 years	76	95	58	59	72	46	196	266	133
40-44 years	95	116	75	71	86	56	263	340	199
45-49 years	119	140	99	88	105	72	345	413	286
50-54 years	145	164	127	107	125	91	440	492	396
55-59 years	174	197	153	130	153	109	547	586	514
60-64 years	204	234	177	157	190	129	616	639	597
65-69 years	220	265	183	175	224	135	633	646	623
70-74 years	218	279	173	179	243	132	591	609	576
75-79 years	183	256	136	154	228	107	496	532	469
80-84 years	128	201	87	111	183	72	310	372	268
85 years and over	43	84	25	40	82	21	71	99	56

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TABLE 3
Primary diagnosis for newly entitled ESRD persons: 1973-80

	1973 and prior	1974	1975	1976	1977	1978	1979	1980
NUMBER OF PERSONS	13,320	6,553	6,805	6,245	7,226	7,505	8,315	9,310
	Percent distribution							
ALL CAUSES	100	100	100	100	100	100	100	100
Glomerulonephritis	36.4	29.2	27.1	24.7	23.5	21.7	21.0	19.7
Primary hypertensive disease	13.2	13.9	15.0	15.8	20.4	22.2	22.1	23.4
Diabetic nephropathy	7.0	11.9	12.2	14.0	15.8	18.0	18.7	21.8
Polycystic kidney disease	8.7	7.5	6.5	7.0	6.7	6.4	6.1	5.9
Collagen vascular disease	1.5	2.0	1.8	1.8	1.3	1.7	1.4	1.4
Interstitial nephritis, hereditary	1.5	1.4	1.0	1.6	1.2	.7	1.0	1.0
Interstitial nephritis, other	12.5	10.4	10.0	9.4	7.2	6.6	6.7	6.4
Analgesic abuse nephropathy	(1)	.1	(1)	.2	1.0	1.0	1.2	1.1
Obstructive uropathy, acquired	.3	.2	.1	.4	2.2	2.5	2.5	2.4
Obstructive uropathy, congenital	1	1	1	.5	1.5	1.3	1.5	1.1
Amyloidosis	(1)	(1)	(1)	.1	.5	.6	.4	.5
Multiple myeloma	1	(1)	1	1	.8	1.0	1.0	1.0
Gouty nephropathy	(1)	(1)	(1)	(1)	.3	.3	.3	.5
Other, unspecified	9.4	12.5	13.3	12.1	7.8	6.5	6.1	5.0
Etiology unknown	9.0	11.0	12.8	12.4	9.6	9.5	10.1	8.8

1 Less than 1 percent.

Reprinted from *HCFA Review* 5:69, 1984.

0000643

TABLE 4
Medicare ESRD program incidence, by diagnosis and age: 1980

	0-14 years	15-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65-74 years	75 years and over
NUMBER OF PERSONS	137	472	1,060	1,113	1,530	2,126	2,065	807
	Percent distribution							
ALL CAUSES	100	100	100	100	100	100	100	100
Glomerulonephritis	37.2	40.0	30.7	24.0	17.6	15.2	14.6	12.6
Primary hypertensive disease	0.0	5.9	11.9	20.0	24.4	25.0	29.1	36.7
Diabetic nephropathy	0.7	5.5	30.8	28.1	24.3	25.9	17.4	10.4
Polycystic kidney disease	6.6	1.1	2.3	7.5	10.7	7.4	4.5	2.0
Collagen vascular disease	2.2	4.7	2.5	2.1	1.4	0.6	0.8	0.4
Interstitial nephritis, hereditary	2.9	4.4	2.2	0.9	0.5	0.7	0.3	0.4
Interstitial nephritis, other	4.4	8.1	5.1	4.1	5.6	6.6	7.1	9.3
Analgesic abuse nephropathy	0.0	0.2	0.1	1.3	1.2	1.7	1.3	0.2
Obstructive uropathy, acquired	0.7	1.1	0.7	0.4	1.4	2.4	4.2	5.8
Obstructive uropathy, congenital	18.2	9.1	2.0	0.6	0.1	0.1	0.1	0.0
Amyloidosis	0.0	0.0	0.0	0.4	0.7	0.7	0.8	0.5
Multiple myeloma	0.0	0.0	0.0	0.4	0.6	1.3	1.9	2.1
Gouty nephropathy	0.7	0.2	0.2	0.2	0.7	0.5	0.6	0.7
Other, unspecified	20.4	13.1	6.4	3.6	3.5	4.3	12.7	4.2
Etiology unknown	5.8	6.6	5.2	6.5	7.2	7.7	4.4	14.6

Reprinted from HCFA Review 5:69, 1984.

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TABLE 5
Cause of death in patients in the first to years
of treatment and thereafter

	Early--First Two Years	After Two Years
Cardiovascular	50.5%	48.8%
CVA	9.4%	9.0%
Hemorrhage	1.5%	3.7%
Infection	13.5%	13.7%
Stop Treatment	12.7%	9.7%
Cancer	2.9%	2.0%

From Blagg CR, Wahl PW, Lamers JY: ASAIO J, 6:170, 1984.

000046

Figure 1 - Patient survival by age.

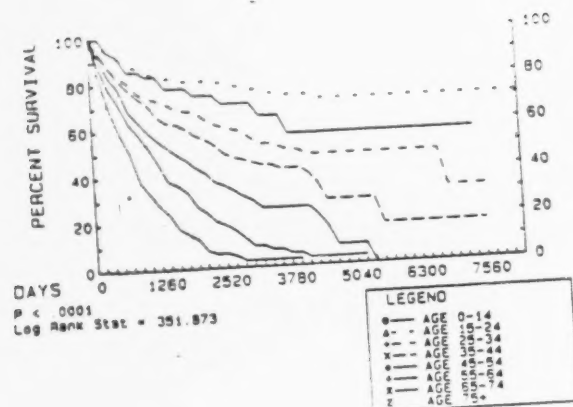
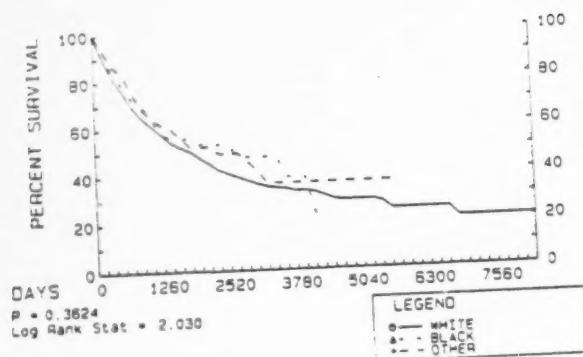


Figure 2 - Patient survival by race.



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Figure 3 - Patient survival by renal failure diagnosis.

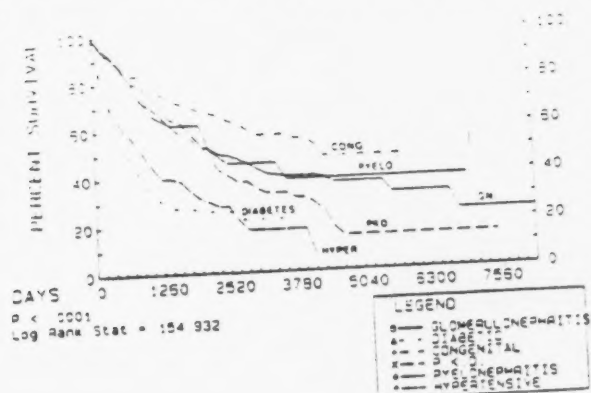
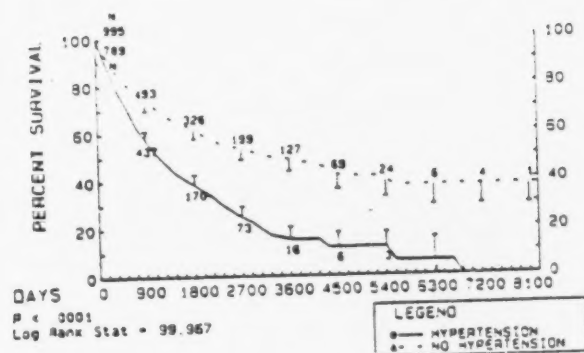


Figure 4 - Patient survival with and without preexisting severe hypertension.



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Figure 5 - Patient survival in patients with and without preexisting cerebrovascular disease.

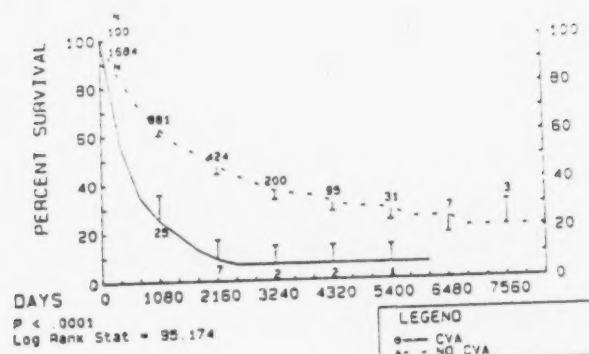


Figure 6 - Patient survival in patients with and without a history of cancer.

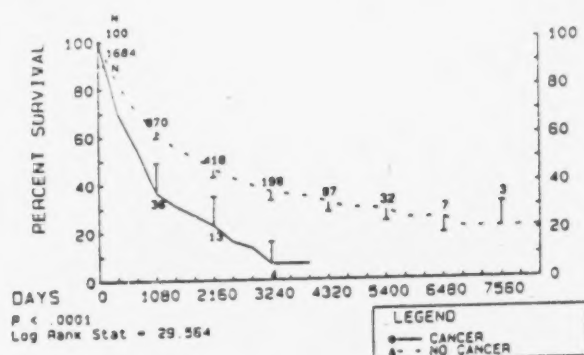


Figure 7 - Patient survival in patients with and without preexisting coronary artery disease.

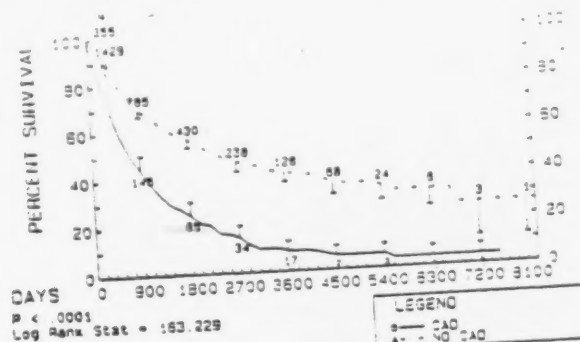
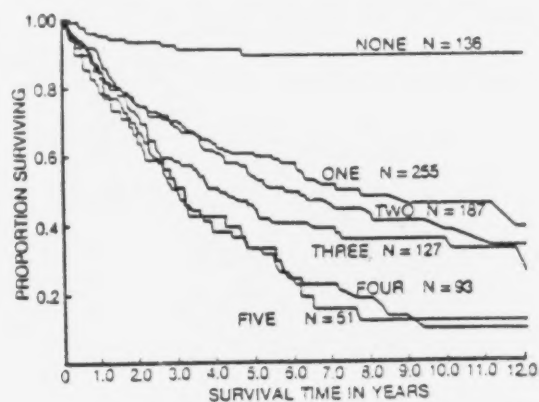


Figure 8 - Patient survival based on number of associated diseases.



RENAL DIALYSIS DECISIONMAKING

000650

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The history of dialysis therapy for kidney failure and the evolution of kidney transplantation have been described by other authors (R. Rettig, Drukker, Parsons and Maher). This analysis focuses on one of the more difficult aspects of the use of artificial life-support systems: the decision to discontinue therapy. The data presented is from the University of Rochester Medical Center for the calendar years 1983 and 1984. The analysis includes all patients treated during these two years.

A formal regional program for the treatment of end stage renal disease (ESRD) patients was established in 1967 in the Rochester metropolitan area. This region has a population of approximately 1.2 million people, is comprised of nine counties including Monroe (Rochester) and extends south to the Pennsylvania border. This area is representative of the composition of the population of the United States in that there is a major urban population, relatively affluent suburban communities, rural and wilderness areas. Reports on the incidence of ESRD patients and projections have been published previously by this author (Freeman, 1975) and colleagues (Cestero, Jacobs, Freeman, 1980).

Decisions to initiate treatment with dialysis are made by review committees in each of six institutions that provide dialysis treatments. The nine county program is coordinated through a larger Dialysis and Transplant Committee established in 1967. This group* meets weekly or bimonthly to review candidates for transplantation, update treatment protocols and establish general policies. Administrative, procedural ethical and social issues are discussed in an open forum. In the early years, the group dealt more with medical acceptability for treatment of individual cases. Since the mid 1970s, the group's attention has turned toward formal policy protocols and the review of cases in which questions of discontinuation of dialysis therapy are raised. A subcommittee studied ethical problems inherent in consideration for termination of treatment for more than a year, 1975 to 1976. The general outcome of the subcommittee's report emphasized the patients freedom of choice. Legal counsel had major input into the subcommittee report and has been sought by the entire group on a continuing basis.

*Disciplines represented on the Dialysis and Transplant Committee include the nephrologist director of each dialysis unit and the director of the medical and surgical transplant programs, the organ preservation team, urology, psychiatry, nursing, tissue typing laboratory, social service, dietary, hospital administration and the clergy. Meetings are open to any responsible medical professional and patients.

To summarize the general policies of acceptance of patients for treatment, every individual who presents with kidney failure receives the right to treatment and to choose the type of treatment they desire. No patient is denied therapy. The individual hospital committees and the interdisciplinary committee may conclude that dialysis treatment may not be in the best interest of a patient as it may result in a prolongation of the dying process. However, if the patient chooses not to accept the recommendation of the committee and is competent, the patient is accepted and every available resource is utilized for treatment without prejudice.

All modalities of therapy are offered and, henceforth, for purposes of this report, they will be referred to simply as dialysis or transplantation. There has never been a discussion or a judgment about the "social worth" of a patient.

All patients under consideration for a renal transplant undergo a lengthy evaluation and are screened for medical, surgical, urologic, social problems and anesthesia risks under a defined protocol. The key members of the Dialysis and Transplant Committee that evaluate potential transplant recipients are a nephrologist, a vascular transplant surgeon, a urologic surgeon, a psychiatrist and a social worker.

The principles of access to therapy and freedom of choice in our community are consonant with the judgments of the Supreme Court that established the penumbra of the right to privacy and self-determination under Common and Constitutional Law (Rowe vs Wade); the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereafter

known as the President's Commission) and the opinions of most ethicists that support equal access to care and freedom of choice.

Decisions to discontinue treatment are not so straightforward. The objective of the patient care team is to address those difficult problems in the context of medical data and social, legal and ethical tenants. No single physician or medical professional can render this decision. There must be common agreement between three qualified physicians and the patient, if competent, or the legal next of kin in patients who are not competent.

DEFINITION OF TERMS

Loss of function of the kidneys to a level that is incompatible with life will be referred to as renal failure. Medical textbooks separate renal failure into two categories: acute renal failure and chronic renal failure.

Acute renal failure is defined as sudden loss of function caused by several hundred diseases, toxins, changes in blood circulation and obstruction to urine flow. Many of these patients may regain natural function of the kidney if they can be supported by the artificial kidney and close medical management. Others die from the underlying disorder that caused kidney failure. Some never regain function but can be maintained by the artificial kidney for an indefinite period. These patients are desperately ill in the early phases of loss of function because the underlying insult to the kidney also affects other organ systems.

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Chronic renal failure is irreversible loss of kidney function from a large

variety of known and unknown causes. Natural kidney function will not return in these cases. These patients have end stage renal disease (ESRD) and decisions to initiate therapy are made before the patient is in danger of dying. These patients are eligible for Medicare benefits after dialysis treatments have started or when they receive a transplant. Discontinuation of treatment of patients on long-term dialysis in this category was analyzed by Neu and Kjellstrand (NEJM 1986; 314:14-19). This is a valuable publication but does not address decisionmaking in patients with acute renal failure.

These textbook definitions are useful only after a diagnosis of the basic disorder has been made. Decisionmaking would be more rational and efficient if the cause of kidney failure were known before dialysis therapy must be initiated. In the real world, individual patients often present with life threatening consequences of kidney failure (uremia), and emergency dialysis treatments must be started before a definite diagnosis is established.

For this reason, new patients have been divided into two groups according to the manner in which they present for diagnosis and treatment: those with sudden renal failure and those with known chronic irreversible renal failure.

Sudden renal failure indicates the urgency and primacy for treatment before a diagnosis of the underlying cause is made. Sudden renal failure is further divided into those cases that follow major surgical procedures and those due to medical conditions to determine outcome and costs. Most studies about decisionmaking focus on patients with chronic irreversible disease (ESRD). This analysis is meant to be comprehensive and includes those patients who are first seen in an emergency situation and require dialysis treatment

before a definitive diagnosis is established. The importance of including these patients is: 1) There is the possibility of recovery of natural kidney function; and, 2) It is the group in whom the largest percentage of patients eventually have a decision made to discontinue treatment.

All of the 228 patients are divided into the following six groups:

- 1) Sudden renal failure following surgery for catastrophic vascular accidents, complex major procedures on the heart that utilize cardio-pulmonary bypass, and operations on two or more major organ systems.
- 2) Kidney failure that occurred suddenly or was not previously known to exist. These are emergency cases that require immediate treatment because they are in danger of dying from retained toxins, fluid overload or chemical imbalance.
- 3) New patients with known kidney disorders that progressed to end stage renal disease in 1983-84. These patients were known to have irreversible chronic renal disease, progressive in nature, and were started on dialysis therapy in 1983 or 1984.
- 4) Patients on maintenance dialysis treatment transferred from other facilities because of complications, intercurrent illnesses or incidental surgical procedures. These patients were on dialysis for months to years prior to the admission for intercurrent problems.
- 5) Patients who received a kidney transplant before the two year study

period, had adequate natural function of the transplant, but had progressive chronic rejection or recurrence of their original disease. These patients returned to maintenance dialysis treatments in 1983-84 to wait for another transplant or to remain on dialysis depending on their preference and their medical condition.

- 6) Patients who received a new kidney transplant during the two year study period.

ANALYSIS OF PATIENT DATA

Data on all patients who received dialysis therapy or who had a renal transplant, during the calendar years 1983 and 1984, were retrieved from the University of Rochester Computer Center by an IBM 4381 Computer in an MVS environment using SAS software. The information used in this analysis is listed in Table I and co-morbid conditions in Table II. The diagnoses, hospital course and discussions of decisions were crosschecked by review of written records of weekly care rounds, minutes of the interdisciplinary Dialysis and Transplant Committee, operating room records, formal patient hospital records and other sources. Fiscal data are true charges, not costs. Diagnosis Related Group (DRG) classification is the principal diagnosis at discharge, not admission.

RESULTS

Two hundred and forty-four patients had 562 admissions for dialysis or transplant in the two year study period. Complete data is not available in 10

patients, 6 patients had 10 admissions for drug overdoses, received treatment by hemoperfusion and are excluded from this analysis. The final population consists of 228 patients who had 537 admissions.

The characteristics of patient groups are summarized in Table III. No statistical analysis of differences between groups is presented because this study is not prospective, no control groups were utilized for age, sex, race, co-morbid conditions or other variables. The true base population characteristics for co-morbid events and hospitalization data are beyond the scope of a study of this type. Further, the groups are not comparable because the purpose of the study is decisionmaking in individual patients who present in a unique manner. Finally, therapy was rendered with different goals for each patient group and, therefore, the groups are not strictly comparable.

A number of known observations are confirmed by the data in Table III. First, the incidence of renal failure in blacks is very high.* Second, the number of diabetics in the irreversible renal failure groups accounts for approximately 1/3 of the total patients. This is in contrast to patients that present with "sudden" renal failure where the percentage of blacks and diabetics are closer to that of the general population.

*The percentage of blacks in Monroe County (Rochester) is 10.1% and of the nine county region 6.8% or 81,264 of 1.2 million. (Data from the 1980 census supplied by the Center for Government Research, Inc.).

Other findings are not surprising. The preponderance of males in the post-surgical "sudden" renal failure group reflects the higher incidence of vascular disease of the coronary arteries and the large vessels that lead to catastrophic events (myocardial infarction, ruptured abdominal aortic aneurysms, bypass procedures, vascular grafts, etc.). More females on maintenance hemodialysis were transferred in for intercurrent illnesses compared to the number of males. Seven of the 19 females required surgery for metabolic bone disease. This is a common complication in patients on long-term dialysis therapy, but more severe in females.

Younger patients received transplants because vascular disease in the elderly exclude consideration for transplantation. The number of co-morbid conditions is less in the transplants but there is a high percentage that are diabetic.

The large diabetic population in the established chronic renal failure and transplant groups may give a false impression that more younger patients receive dialysis and transplant treatments. Early onset diabetes (juvenile diabetes) occurs early in life and complications occur in midlife. Renal failure is the major life threatening complication in 50% of these patients. Thus, the incidence of diabetes moves the age scale toward younger persons, e.g. those below age 65.

The number of co-morbid conditions is roughly the same in each group except the new transplants. This data is probably of little value except to demonstrate that virtually all patients have one or more disorders other than renal failure. In fact, only 4 of the 228 patients were free of major

complications of renal failure and diseases of other organs. It is the type and severity of the co-morbid condition that determines the outcome, not the number. For example, severe coronary artery disease is more serious than anemia or low back pain.

Because the process of decisionmaking is the subject of this report, one observation from Table III is emphasized. Forty-two percent (95 of 228) patients were not known to have renal disease by the medical staff or the referring physician when they first appeared for diagnosis and treatment. These patients with "sudden" renal failure were critically ill and in danger of dying from chemical imbalance, fluid overload, or retained lethal toxins at the time of presentation. In these individuals, the primary diagnosis becomes a secondary consideration and the immediate directive is to restore the chemical and fluid status of the patient to less dangerous levels by initiation of dialysis. After one or more treatments, definitive studies are conducted to determine the cause of renal failure and whether or not there is the potential for recovery of natural kidney function.

If the new transplants are excluded from the total group, then 53% of all patients fall into the "sudden" renal failure group. If only patients started on dialysis therapy for the first time are considered, those with an uncertain outcome represent 69% (95 of 137) of all new patients treated at Strong Memorial Hospital (SMH).

This institution is the Hospital of the University of Rochester Medical Center and the major Tertiary Care Center in this area. It is possible that the percentage of new cases that are "sudden" or acute renal failure is higher

than might be representative for the region.

The exact number of new ESRD cases started on dialysis in the nine county area in 1983-84 was 200.* Twelve of these came from the "sudden" renal failure group and 42 from the new chronic renal failure group started on treatment at SMH. The remaining 83 cases of sudden renal failure regained natural function or died (Table IV).

Not all "sudden" or acute renal failure cases occur or are referred to SMH so the figure of 83 cases with the potential to recover function, who will die of their basic disease or in whom a decision must be made to discontinue therapy is a minimum number. The conclusion is that at least 30% of all new patients started on dialysis therapy may not have had a diagnosis established and the outcome is unknown at the outset.

Data on patient outcome (Table IV) confirms this point. A decision to withdraw treatment was agreed upon in 24% of the patients who presented with "sudden" renal failure (23 of 95), the largest portion in any of the patient categories. However, just under 30% of patients with "sudden" renal failure had return of natural function and were eventually discharged from the hospital without the need for support with the artificial kidney. Thirty-four percent died and 13% remained on chronic dialysis.

*There were 110 new ESRD cases started on dialysis in 1983 and 90 in 1984. The incidence is 92 and 75 cases per million population. The 1985 incidence was just over 100 cases per million.

Table IV is a summary of the outcome of the six groups. Tables V through IX summarize subgroups according to age, sex, length of hospital stay for the procedure or occurrence of kidney failure or transplant, additional admissions and hospital charges. Table X compares mean hospital charges per patient for each of the subgroups and Table XI is a computer printout of the DRG classification of the patient admission analyzed in this study.

Transplant candidates are encouraged to continue on dialysis if they have significant vascular, pulmonary or other disorders that may jeopardize their life because of the side effects of continuous immunosuppressive therapy. They are not excluded, however, if there is a reasonable chance of success. The higher risk is supported by the characteristics of the three deaths in the transplant group: all were diabetic and over 50 years of age.

Excluding the transplants, 69% of the patients were over 50 years of age and 35% were over 65. Other findings are evident from the tables. Length of stay and hospital charges were highest for those with the most serious illnesses: those with "sudden" renal failure following surgical and medical procedures. A deliberate decision to discontinue treatment made no difference in the length of stay or hospital charges when the patients are compared as groups. All data is available from the tables or can be calculated from the information provided.

In group 3, known patients with irreversible disease, three died and two discontinued treatment. The 12% mortality rate is consonant with national figures and significantly lower than the "sudden" renal failure group. The three deaths on dialysis were due to non-renal complications that occurred

after therapy was initiated. In two, therapy was withdrawn by common agreement 43 and 57 days after the first dialysis. From the beginning of therapy, there was an understanding of the expectations by the patient.

The first patient, with irreversible disease in whom treatment was discontinued, was a 67-year-old female with severe hypertension and coronary artery disease. There was an understanding at the begining that there would be a 4 week trial of therapy and treatment would be discontinued if, in her view, she failed to have significant improvement of her angina and congestive heart failure. Unfortunately, there was no improvement and treatment was discontinued. The other patient, a 70-year-old woman, had obstruction of urine flow from a pelvic cancer. She was advised that chemotherapy was unlikely to cause regression of the tumor though her kidneys had been irreparably damaged. When the tumor failed to respond to treatment, she requested that dialysis therapy be discontinued. She was judged to be mentally competent and her request was granted. Data on the other patient groups is contained in the tables.

DECISIONS TO BEGIN DIALYSIS

As stated, all persons who are in danger of dying because of the consequences of kidney failure of unknown cause received dialysis as discussed above.

There are individuals with known progressive disease who chose not to have dialysis or are never referred for treatment. This is not uncommon but the exact number is unknown.

DECISIONMAKING

Thoughtful people are likely to agree that the multitude of variables crucial to decisionmaking for patient care cannot be captured by a cool analysis of statistics of patient outcomes, costs, co-morbid conditions, fear of litigation and societal pressures. The drama of each individual life cycle is a dynamic course of known and unknown variations in the essence of being. The ebb and surge of courage and fear, satisfaction and contempt, arrogance and humility occur in everyone. These conscious emotions are not reflected in the tables. The nature of humans is singular.

A man of sound mind, 77 years old, has known for many years that his kidney disease is progressing toward death from accumulation of toxins. His trust in two physicians and the maze of the medical care system caused him to follow a program of conservative measures that restricted his freedom to enjoy retirement. Conservative treatment has prolonged his life for a year or more free of artificial life-support systems. Gradually, however, over the last year, he has begun to recite the early symptoms of kidney failure. His tolerance for exercise is decreased and his ability to concentrate for prolonged periods of time has deteriorated.

He knows about artificial devices that might prolong his life. His wife and he have discussed whether or not he should have a trial of therapy. But he has accepted the natural course of his affliction and sits side by side with his beloved companion of 50 or more years and states that he does not wish to have treatment.

He appears content, but at times anxious. What will be the symptom that heralds his demise? He calls on occasion to inquire whether this or that is the beginning of the end. Most of these symptoms are trivial but to the patient they do not seem so trivial until reassured. He is not an eccentric nor is he psychologically disturbed in any way. His kindly and soft demeanor is accepting.

When told that the end will be soon, perhaps within months, the couple trust and wait. They grow closer.

He has exercised his freedom of choice.

Mr. WK is a 49-year-old diabetic with progressive renal failure. He is legally blind from diabetic retinopathy and can make out shadows only. He has severe degenerative disease of his peripheral nerves so that he has very little pain or pressure sensation in his lower extremities. Because of the loss of sensation, a chronic pressure ulcer developed on the heel of his left foot. The likelihood of healing this ulcer is marginal because of the poor circulation to both feet. He has had one myocardial infarction. His appearance is that of a man 20 years older than his true chronologic age.

He was admitted to the Intensive Care Unit because of diabetic keto-acidosis in coma. His blood sugar was controlled with repeated doses of insulin and his fluid balance was gradually restored to normal. About 10 days after his coma cleared, he was informed that his kidney function was 15% of normal and progression of his disease was almost

certain.

The patient, his wife and two sons were told the details of dialysis treatment. A fistula would have to be created; treatment would be four hours three times a week; wide variations in his blood sugar were likely; leg cramps and generalized fatigue would probably follow each treatment. The patient's wife and the sons toured the Dialysis Unit and the details of each procedure were explained to them. The same details were also described to the patient. The opinion of three physicians was that he was not a candidate for transplantation because vascular disease would not allow connection of blood vessels from a donor kidney to his own arteriosclerotic vessels.

Mr. K never waived from his determination to live as many years or months as possible. His answer to the suggestion that treatment may prolong his pain, that amputation may be necessary if his foot ulcer became infected, that he may have another heart attack or other vascular occlusions has been the same: "Doctor, if I can have a few extra months or years with my wife and sons and enjoy the sound of my grandchildren at play, I want dialysis".

His stately wife assures us that she will provide her husband with every detail of care. Each of his sons insist they will alternate the responsibility to bring him to a center for dialysis. The patient and each member of his family have been told again and again that dialysis will not cure or even improve his vascular

disease. But at the conclusion of each discussion, the family is certain to thank every member of the health care team and to remind us in a quiet and respected manner that Mr. K wants to live and they will be most grateful if we will extend to him treatment for his kidney failure.

Mr. K will be started as his fistula has been created and is ready for use. What cannot be described adequately is the acceptance, trust, courage, love and gratitude of the patient and his family.

In 1975, the Chairman of the Dialysis and Transplant Committee (the author) raised two issues for consideration of the Committee:

1. Given the theoretic possibility that facilities for dialysis treatments may be inadequate for all ESRD patients, how would the community cope with the situation in terms of selection of patients for treatment?

2. What should be the proper and accepted process to discontinue treatment in those patients already started on dialysis therapy who sustained complications that rendered them infirm, dissatisfied or incompetent mentally?

A Subcommittee was appointed to discuss these issues and other issues. The Chairman was the Cannon Reverend Nathaniel Whitcomb, a distinguished scholar of the Episcopal Church and Protestant Chaplain to Strong Memorial Hospital. The group also included Dr. William A. Greene, distinguished Professor of Medicine and Psychiatry, member of the Medicine-Psychiatry Liaison Group and of the original Gottschalk Committee that was convened by the Bureau of the Budget

in 1967 to consider the phenomena of prolonged life-support with the artificial kidney. Other members of the committee included the Catholic Chaplain to the hospital, a practicing nephrologist, a transplant surgeon, an anesthesiologist, a nurse, and a social worker.

The Subcommittee addressed a "coping" process, which actually was a prospecting method of determining how well patients fared on dialysis treatment. The acceptance of patients into the Dialysis and Transplant Program has never been a problem. As stated previously, all patients receive therapy under free choice unless the individual refuses dialysis and is judged to be competent and rational, or has made a clear statement when competent that they do not wish to have therapy if the "need" arises and they are not competent. The committee's draft report contains a discussion on the discontinuation of treatment including recommendations from legal counsel. The full draft report is attached in the Appendix.

The Subcommittee identified clearly the difference in consideration of beginning therapy and the legal and moral responsibilities of medical professionals after treatment had been started. The deliberation of the Subcommittee emphasized what is "standard of care in the community", the gravity of the need for medical professionals to offer all available help and to honor "the rational convictions of the right to control ones life with the concomitant right to exercise that decision".

At that time (1976), there were few legal or moral guidelines regarding discussions to discontinue treatment.

In the ensuing 10 years, the approach has evolved into a verbal contract between medical professionals and patients, if competent, or the legal next of kin in incompetent patients. This approach has been useful, particularly in patients with "sudden" renal failure, when the exact diagnosis and the possibility for recovery of natural renal function are not known at the time of presentation. It is also of value in those chronic patients on dialysis treatments who sustain complications such as cerebral vascular accidents, progressive heart disease, or developed neoplasms after they have been on dialysis treatments for months or years.

An agreement on a trial period of intensive treatment allows the medical professionals time to establish as exact a diagnosis as possible and to adjust therapy to an optimal level to allow maximal rehabilitation. The trial period also allows the patient and the family time to come to grips with the gravity of a decision to discontinue treatment.

The following are two examples of extremes encountered in this approach.

A 69-year-old widowed female was started on maintenance hemodialysis in a hospital in a distant city 6 months before transfer to Strong Memorial Hospital. She had a history of hypertension, adult onset diabetes, and had had several myocardial infarctions. She had angina at rest on admission.

She moved to Rochester to live with her married daughter and to receive consultations from cardiologists and nephrologists.

Initially, the patient was restricted to bed by the limitations of her heart disease as she became short of breath and developed chest pain on the least exertion. After diagnostic studies, her dialysis treatments were altered to adjust fluid volume to minimize fluid overload of the heart and other adjustments were made in her medications to improve cardiac function. During the first week, the cardiologist, nephrologist, dialysis nurses, social workers, and others discussed her personal, medical, and social situations with the patient, the daughter and son-in-law.

When it was evident to all that the likelihood of improvement was nil, the concept of a trial of maximum therapy for a finite period was raised first with the daughter, the son-in-law, and then with the patient.

These interactions are delicate and sensitive. They are initiated on an individual basis depending on the presentation of the patient and their situation. In this case, the approach to the patient began: " Mrs. _____, it is difficult to come into a person's life for only a small fraction of your 69 years and begin a conversation about your very serious condition". The patient accepted the concept of a trial of intensive therapy with the understanding that a complete re-evaluation of her entire status would be made at the end of four weeks of intensive treatment. Nothing more was said for four weeks regarding the re-evaluation, except to answer the questions of the patient and the family and to explain why certain adjustments in the treatment program were made.

At the end of a full month, the patient was still unable to move out of

bed without severe chest pain and shortness of breath. The daughter's home situation had been judged to be excellent, the son-in-law had expressed his support of his wife to care for his mother-in-law in separate private conversations. Then, privately, the two volunteered jointly that the patient would be accepted with loving care into their home.

Subsequently, the patient was informed that there was little hope for improvement in her condition by a single physician. Later in the conversation, as planned, the patient and the physician were joined by the daughter-in-law and husband. This was done to assure the patient that the daughter and son-in-law understood her problem and wanted her to come home with them. Eventually, the woman decided that she would be more comfortable in her daughter's home for her last few weeks. The emotions of this discussion were intense and when it was over, there were tears on everyone's cheeks.

She died 19 days after discharge in the daughter's home.

At the other end of the spectrum, sharing and trust are not easily accomplished.

A widowed female, age 66, had been on maintenance dialysis for 8 years. In 1978, she suffered a cerebral vascular accident with left hemiparesis. In 1983, she sustained a right-sided paralysis leaving the woman unable to communicate or to perform the most simple task.

Her heart was unstable requiring monitors and other resources available only on the Medical Intensive Care Unit.

The nephrologist who had referred the patient to Strong Memorial Hospital after the second vascular accident, had tried to bring the four sons together to discuss further treatment and had contacted legal and state authorities regarding the possibility of discontinuing treatment without consent of the four sons. These efforts were continued after the second cerebral vascular accident when the patient was admitted to Strong Memorial Hospital. Three of the sons remained adamant that every possible treatment should be continued for their mother.

The medical professionals had all agreed that the outlook for recovery to a meaningful existence was hopeless.

Without consent of the legal next of kin, however, no one believed that they had the ethical or legal right to discontinue treatment. The woman remained hospitalized for a total of 69 days, mostly on the Intensive Care Unit and finally died of overwhelming sepsis. Dialysis therapy was continued to the very last day before death.

In 67 other cases in this study that died, there was a distinct different scenario for each individual case. Unlike the report of Neu and Kjellstrand, there is no identifiable decisionmaker about discontinuation of treatment unless it was the patient. Even then, there were frequent reversals of decisions once made with firm conviction. The cases listed as dialysis discontinued are largely those who were incompetent or a few who never waived from their decision to have treatment discontinued. There are only two axioms

that apply to all of the cases in this analysis: 1) The patient was allowed freedom of choice or in the case of patients mentally incompetent, documentation that the patient would have exercised a choice to continue or discontinue therapy was required before a decision was reached by the health care team to continue or discontinue treatment. 2) In any patient where there was even the slightest hint of litigation, every possible measure to treat the patient was followed despite personal or collective convictions by the medical professionals that treatment was not appropriate.

Thus, decisionmaking has evolved from the more paternalistic and authoritarian tone of the report of the Subcommittee of 1976 to one of freedom of self-determination by the patient. And, as medical liability has become more costly and threatening, the health care team increases efforts to avoid litigation, regardless of cost, despite the recognition that cost containment is a responsibility of all concerned.

In the face of these conflicting pressures, there are many cases in which patients and families have had positive benefits that defy quantitation.

A 70-year-old executive was started on regular dialysis therapy for ESRD due to hypertensive kidney disease (nephrosclerosis) in 1978. This courageous man traveled extensively through Europe and the United States, continued to manage his business and was active socially for four and a half years. His last six months were difficult because of the progression of bone disease and heart failure. However, during the five years on dialysis treatment, he trained his son to manage the family business, earned the respect and love of his son and left his firm and its employees

in its most positive and financially secure position in its history.

A 62-year-old man had a kidney removed in 1977 because of a malignant tumor limited to that single kidney. It is not uncommon that this type of tumor recurs in the other kidney, and a second tumor appeared in the remaining kidney in 1983. This kidney was resected successfully with the patient on dialysis therapy, and he remains in relatively good health to this date.

A 13-year-old male was known to have nephritis for two years which caused massive loss of protein in his urine and modest loss of kidney function. He was transferred to the Pediatric Intensive Care Unit with massive fluid retention that restricted his ability to breathe, decreased his cardiac output and caused rents in the skin of his extremities and trunk with weeping fluid. Both eyes were closed because of the fluid collected in the subcutaneous tissue in his face. He was started on dialysis to remove fluid but with a full recognition that his marginal kidney function would fail completely as it almost always does when dialysis is initiated. This was a purposeful decision since the object was to prevent loss of protein in the urine which would directly improve the severe state of fluid retention. After multiple dialyses, surgical procedures to drain fluid and several episodes of infection, he was discharged after six weeks on a regular dialysis program. Six months later, he began to produce small amounts of urine that were relatively free of protein. He gradually increased his urine output eventually reaching 40% of normal function without the need for dialysis. Why he recovered function spontaneously is not known but he is well today and

leads a relatively normal life.

Although the latter case is unusual, it is by no means rare. In addition to this case, four others with known renal disease of uncertain cause had kidney failure that at times required treatment with the artificial kidney over the two year study period. In these patients, the activity of their kidney disease waxed and waned allowing periods of months off of dialysis but having to return when the function declined. These cases resemble kidney transplants that undergo episodes of rejection that may or may not be reversible with anti-rejection therapy. The difference is that the cause of these primary chronic diseases of the kidneys is unknown, and the mechanisms whereby natural function returns has not yet been identified.

Types of cases are categorized below. This organization of groups is meant to illustrate some, but not all, of the variables in decisionmaking. It is done at the risk of giving an impression that each case is not individualized.

- 1) Therapy is discontinued after a trial period under verbal contract with the patient, if competent, or the next of kin if the patient is mentally incompetent.
- 2) Patients may undergo an unexpected improvement in function such as illustrated by the last case described above.
- 3) Patients may have unexpected benefits that are never known to the medical care team that relate to the positive effect on the family,

employees or other friends.

- 4) Dialysis allows new benefits to patients such as the removal of both kidneys for tumors that usually appear only in the kidneys and eventually will metastasize.
- 5) Patient equivocation occurs frequently where the will to live and the desire to give up constantly change making a clear plan for re-evaluation difficult.
- 6) Physician equivocation occurs in some cases. Here, a referring physician may not allow the medical team to enter into a contract with a patient or may fail to allow a "do not resuscitate" order in the patient's chart.
- 7) Patients may not be able to come to grips with a decision regarding discontinuation of therapy or the family may equivocate as described in one case example above. In these cases, dialysis is continued indefinitely.
- 8) Patients may have unrealistic expectations of the results of treatment, become depressed, do not make full efforts to become rehabilitated and continue on treatment without significant improvement.
- 9) Patients may be unable to cope with complications, have a downhill course and die.

- (10) Very difficult patients have unreasonable demands that continue to annoy the health professionals and at times disrupt optimal care. The most difficult examples are transplant recipients who discontinue their immunosuppressive drugs after years of a successful functioning transplant. They become convinced that there is no need for continuation of anti-rejection therapy. Obviously, the kidney rejects and the patient returns to dialysis.
- (11) Some patients are in uncharted territory, and the outcome of the disease is unknown to professionals. We simply know too little about too many disorders.

As with any summary, there are areas that probably require expansion or where there is significant overlap.

THE REALITY OF DIALYSIS TREATMENT

Throughout this report, the concept that each individual is unique has been emphasized. Categorization of patients or of medical professionals is fraught with problems of an infinite number of variables. On the other hand, the analysis of cases as individuals without statistical scrutiny leaves any report open to valid criticisms. This report could be criticized as a series of anecdotes of a method of personalized delivery of care.

Illustrative of problems in decisionmaking by case vignettes emphasizes uncertainties of biologic events and adaptation to treatment. The traditional approach is to organize patients into groups according to the manner in which

they present and by their outcome. This results in depersonalization of a report.

In accord with the opinion of others, the value of anecdotes is very useful to supplement an organized analysis (see President's Commission, specifically, Moran's objection to the value of anecdotes, page 8; and Commission on Valentine, page 201, volume 1). Though an attempt has been made to utilize the categorization approach, it has been supplemented with anecdotal presentations to illustrate the personalization of treatment. As Cassels (NEJM 1982; 306:639-645) points out, each person has dimensions beyond values and beliefs: each person has his own personality trait and behavior pattern with which they address an illness; a person has a past, memories and skills learned, without which they are incomplete; life experiences, particularly of previous illnesses bear on their perception of medicine as a science or an art; their family is a part of their person; cultural background dictates their attitudes to a host of variables; the individual has roles important to him or her and has a particular way of relating to others. Each person is political, creative, ignorant of new changes in their environment and has certain creative behavior patterns. Each patient has a strong image of their own body and the fear of how it may be altered by illness. Each individual has fantasies that are shared with no one and has a "perceived" future in which "hope dwells". Each person has a "transcendent dimension, a life of the spirit" which may or may not be religious or mystical.

A second reality that has been emphasized in this report is the difference in discontinuing treatment in patients in whom dialysis has already been started compared to the patient not yet treated. At least two features of this

dilemma deserve comment.

First, there is the uncertainty of the outcome. There are publications pertaining to uncertainty by medical professionals and their failure to relate this uncertainty to patients (Fox, Drummond). There is only one certain fact and that is that someday we will all die. Otherwise, there are no absolutes in the responsible practice of medicine. One speaks in terms of percentages: that there is a 95% chance that a live-related donor transplant will be functioning at the end of one year or that the mortality rate of all patients started on dialysis is 15% per year. However, for the individual with a given illness, there are no guarantees and it is the foolish person who speaks in terms of no risks or no hope. Those that develop criteria to predict an outcome of 100% must be viewed with extreme caution. For example, two recent publications emphasized age as a major variable that predicts a poor outcome (Rosmussen, et al: Arch Intern Med 1985; 145:2015-2018, and Lien and Chan: Arch Intern Med 1985; 145:2067-2069). There are 10 examples of contradictions to "predictive factors" of inevitable death in this report alone. Unexplained deviations from the expected outcome occur everyday in every institution in the world and countless times in the career of a busy practitioner. Presentation of percentages is of some benefit to the individual patient to assist in reaching a decision but for that person the percentage of success or failure will be 0 or 100%.

The events that have to do with the course of nature are always uncertain despite the highest level of expertise of medical professionals. The greater the lack of scientific knowledge, the more likely is the uncertainty. Finally, knowledge need not necessarily be hidden from a patient, but it may be impossible to communicate with certain individuals since we all have

imperfections of perception.

In this group of patients, there were many uncertainties particularly in the first two groups. But there is the singular assurance that virtually all would be dead, irretrievably dead, if they had not receive the life-support treatments under scrutiny here.

Thus, the tendency was strong to err to treat too many persons rather than too few. This tendency was regardless of the age of the patient or the numbers of complications except for those where procedures could not be conducted because of technical problems.

Second, there is a lack of definition of what dialysis does. Dialysis replaces the function of a vital organ system: the kidneys. Dialysis is by no means perfect in its role of replacement. It must be defined as a series of procedures that replace the function of a vital organ system. This is quite different than a respirator or pacemaker because these are devices that assist an existing organ. If the lungs fail completely, a respirator cannot replace pulmonary function. A pacemaker is useless without a viable heart. At this writing, the artificial heart is an experimental device not yet proven for routine use.

There are only two analogies that are, or were, in regular clinical use. The artificial lung was used in patients with poliomyelitis when the nerves that innervate the respiratory muscles were affected and respiration ceased. The "iron lung" replaced the function of the muscles of respiration. It has often been used as an analogy to dialysis therapy. The second is insulin

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therapy in diabetes mellitus, particularly juvenile onset diabetes. The cause of diabetes is loss of function of the islets of Langerhans and the resultant lack of insulin to sustain life. As far as known in this society, it is not conscionable to withdraw insulin therapy and allow death to occur from hyperglycemia or ketoacidosis coma. Likewise, it was not customary to withdraw the artificial lung in the poliomyelitis cases.

The concern about withdrawing dialysis treatment is then clear. To emphasize the point in the extreme, the question is whether there is such a thing as a natural death from kidney failure in the era when artificial kidneys are in common use?

Is there a moral imperative here? If the answer lies in the basic right to privacy and self-determination, then the decision resides with the individual patient. If the patient is incompetent, then the decision is left to others. There is no ethical precedent here except to do what is right, a woefully ill-defined charge.

In the State of Massachusetts, the Supreme Judicial Court ruled that the matter of withdrawing dialysis therapy is a matter for the Court to decide even though the next of kin and the physician have agreed that the most reasonable course was to discontinue treatment in an individual judged to be incompetent (the matter of Earl and Springs, Mass., 405NE2d 115, 1980). This is the only Massachusetts case that addressed dialysis therapy in incompetent individuals. Other decisions in that state are consistent about life-support systems in individuals unable to make their own decisions (Sakowicz to Brophy).

If this precedent is followed, the courts will indeed have their hands full. The cases presented in this report indicate that 30 cases would have been presented to the courts in this area in 1983-84 for dialysis cases only. In the usual course of judicial events, many would not have received final judgment as of the writing of this report.

Consideration of alternatives inevitably leads to the Congress of the United States. Recommendations for action are presumptuous except to observe that responsible decisionmaking in matters that are clearly life and death situations is upon us.

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REPORT ON THE TREATMENT OF ELDERLY PATIENTS
BY DIALYSIS AND TRANSPLANTATION IN EUROPE

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EUROPEAN DIALYSIS AND TRANSPLANT ASSOCIATION

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Introduction

The Registry of the European Dialysis and Transplant Association - European Renal Association (EDTA Registry) is an organisation which collects information on patients receiving treatment for end stage renal failure (ESRF) by dialysis and transplantation in over 30 countries in mainland Europe and on the Mediterranean seaboard. The Registry collects its data by means of an annual centre and patient questionnaire. The centre questionnaire requests summary information on the activity of individual dialysis and transplant units over a 12 month period. A patient questionnaire is completed for every patient accepted for dialysis and transplantation and includes information on age, sex, cause of ESRF (primary renal disease), and most important of all, method of treatment. Each year, individual centres are responsible for registering new patients and updating information on patients previously reported. The update will include a record of any changes in method of treatment, details of transplantation, for example type of graft and drugs used to prevent rejection, details of parathyroidectomy, malignancy and where appropriate, cause of death. The Registry now holds records of over 150,000 patients treated by dialysis and transplantation in Europe. Of these, about 90,000 were recorded alive on treatment at the end of 1983. Copies of the centre and patient questionnaire for 1983 are attached to this report.

The EDTA Registry is a research organisation run by clinicians for clinicians. It is funded with support from the parent European Dialysis and Transplant Association - European Renal Association, together with contributions from national governments and commercial companies. The Registry provides demographic data to a number of governments and regional organisations in

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the member countries. In addition it deals with individual requests from clinicians and renal units. The results of the Registry's research are published in an annual Report and in medical journals.

The Office of Technology Assessment of the Congress of the United States has commissioned the Registry to carry out a study of the treatment of elderly patients by dialysis and transplantation in Europe. "Elderly" has been interpreted as those commencing first renal replacement therapy aged 65 years and above. The report is divided into seven parts. The first deals with demography, the second with the diseases leading to ESRF, the third the choice of therapy for elderly patients, the fourth the balance of therapies in this group of subjects, the fifth causes of death, the sixth the survival of elderly patients on renal replacement therapy and the last, peritonitis, a special complication of patients being treated by continuous ambulatory peritoneal dialysis. Most of the results that are presented come from the individual patient questionnaire and deal with the years 1974 - 83.

1. Demography of Treatment

The numbers of patients aged 65 and over at first renal replacement therapy (RRT) has grown steadily over the decade 1974-83. In 1974 only 321 elderly patients were accepted onto treatment programmes compared to 3,485 in 1983. On 31st December 1983, the Registry had records of over 8,500 patients alive on treatment who had commenced therapy aged 65 and over.

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YEAR	AGE AND SEX DISTRIBUTION NEW PATIENTS (%)								
	<15			15 - 64			65 AND OVER		
	M	F	TOTAL	M	F	TOTAL	M	F	TOTAL
1974	1.5	1.3	2.8	56.4	37.0	93.4	2.3	1.5	3.8
1975	1.5	1.3	2.8	54.9	36.9	91.8	3.3	2.1	5.4
1976	1.5	1.4	2.9	53.8	35.7	89.5	4.5	3.1	7.6
1977	1.3	1.3	2.6	52.3	35.5	87.8	5.6	4.0	9.6
1978	1.4	1.5	2.9	50.9	35.2	86.1	6.6	4.4	11.0
1979	1.6	1.2	2.8	50.5	33.8	84.3	7.1	5.8	12.9
1980	1.4	1.2	2.6	48.7	33.8	82.5	8.6	6.2	14.8
1981	1.4	1.1	2.5	48.5	33.2	81.7	9.0	6.8	15.8
1982	1.4	1.1	2.5	47.9	32.9	80.8	9.2	7.6	16.8
1983	1.4	1.2	2.6	47.3	32.6	79.9	9.8	7.8	17.6

Table I. Proportional distribution by sex and age at start of treatment of new patients commencing renal replacement therapy in each of the years 1974-83.

Table I shows the age and sex distribution of new patients (as a percentage) accepted for RRT in the years 1974-83. Three age groups are given; patients aged less than 15 at first therapy, those aged 15 - 64, and those aged 65 and above. Males and females are shown separately for each age group. The proportion of new patients who are elderly has grown from 3.8% in 1974 to 17.6% in 1983. There is a preponderance in the absolute numbers of males in each age group, though this is less marked amongst children. In 1983 almost 10% of all new patients were males aged 65 and over. As the numbers of elderly patients accepted for treatment of ESRF in Europe by dialysis and

transplantation has grown, so too has the proportion of very elderly, in other words those aged 75 and over (Table II). Table III shows the age distribution of patients aged 65 and above according to year of first treatment. The proportion of these patients aged 75 and over reached 22.3% of the over 65's in 1983.

AGE AND SEX DISTRIBUTION AS % ALL NEW PATIENTS						
YEAR	65 - 74			75 AND OVER		
	M	F	TOTAL	M	F	TOTAL
1974	2.3	1.5	3.8	<0.1	0	<0.1
1975	3.2	2.0	5.2	0.1	<0.1	0.1
1976	4.2	2.9	7.1	0.3	0.2	0.5
1977	5.2	3.7	8.9	0.5	0.3	0.8
1978	5.9	4.0	9.9	0.7	0.4	1.1
1979	6.2	5.2	11.4	0.9	0.6	1.5
1980	7.5	5.5	13.0	1.1	0.7	1.8
1981	7.5	5.8	13.3	1.5	1.0	2.5
1982	7.5	6.3	13.8	1.7	1.2	2.9
1983	7.8	6.1	13.9	2.0	1.7	3.7

Table II. Proportional distribution by sex and age at start of treatment of new patients commencing renal replacement therapy 1974 - 83, aged 65 and over.

000691

YEAR 1ST RRT	AGE AT 1ST RRT (%)	
	65-74	75 AND OVER
1974	99.1	0.9
1975	93.5	6.5
1976	91.0	9.0
1977	90.6	9.4
1978	88.5	11.5
1979	87.5	12.5
1980	85.9	14.1
1981	82.6	17.4
1982	80.5	19.5
1983	77.7	22.3

Table III. Proportional distribution of new patients commencing renal replacement therapy aged 65 and over in each of the years 1974-83.

Although there is a clear trend to the acceptance of more elderly patients onto treatment programmes in most European countries, practice still varies greatly from one to the other. Table IV is based on the 1983 centre questionnaire and shows the total number of new patients, ^{of all ages} accepted onto treatment programmes by country in 1983. Both absolute numbers and the acceptance rate per million population (pmp) are given. It is clear that treatment rates vary greatly from country to country. In Spain, ^{Belgium} and Sweden, for example, the acceptance rate exceeded 60 pmp in 1983 compared to 55.1

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Country	1983	
	N	Per Million Population
Algeria	25	1.4
Austria	402	53.6
Belgium	598	61.0
Bulgaria	254	28.2
Cyprus	19	31.7
Czechoslovakia	315	20.7
Denmark	206	40.4
Egypt	301	7.7
Fed Rep Germany	3,416	55.8
Finland	220	45.3
France	2,366	44.3
German Dem Rep	466	27.7
Greece	379	40.8
Hungary	128	12.0
Iceland	1	5.0
Ireland	80	24.2
Israel	254	66.8
Italy	2,586	45.5
Libya	0	0
Luxembourg	29	72.5
Netherlands	640	45.7
Norway	222	54.1
Poland	285	8.1
Portugal	399	40.7
Spain	2,267	61.3
Sweden	510	61.4
Switzerland	358	55.1
Tunisia	50	8.1
Turkey	319	7.2
United Kingdom	1,865	33.4
Yugoslavia	703	32.0
Total Registry	19,668	34.3

Table IV. Summary of new patients accepted onto renal replacement therapy during 1983 in individual European countries. Both absolute numbers (N) and acceptance rates per million population are shown.

all ages

in Switzerland, 40.4 in Denmark, 33.4 in the United Kingdom and under 30 in the German Democratic Republic. This reflects great variation in available facilities for treatment of ESRF in different countries. It is estimated that in the United Kingdom alone, in excess of 2,000 patients die each year because of untreated chronic renal failure (1).

In countries where services are limited, it seems that the elderly and those with multi-system disease such as diabetes are the last to be treated. Table V compares the age and sex specific acceptance rates for patients aged 65 and over at first treatment in 1983 in 24 selected European countries. An age and sex specific acceptance rate expresses the number of patients taken on to treatment relative to the total number of patients in the population in that age and sex category. The table also shows the absolute number of patients accepted in 1983 (N). Treatment rates vary greatly. Three countries accepted more than 120 new elderly patients pmp, but the majority took on less than 100 pmp and some, like the United Kingdom, Ireland and Socialist nations of Eastern Europe, took on 22 pmp or less. The take on rate for elderly males exceeds that for females in all countries with the exception of Austria. The discrepancy may in part reflect differences in the occurrence of chronic renal failure in males and females (2), but this does not appear to be the sole explanation. Chronic renal failure is said to be more common in males than females in the ratio 3:2, but in Sweden, for example, the acceptance rate for males in 1983 was 140 compared to only 52.8 for females. Similarly, in Israel, the take on rate for males was 272.2 compared to 62.1 for females.

In Table VI the age specific acceptance rates for 1983 have been calculated to show results for patients aged 65 to 74, and 75 and above, separately.

000601

COUNTRY	ACCEPTANCE RATE ≥ 65 / 10^6 POPULATION 1983		
	M	F	ALL (N)
AUSTRIA	48.7	50.6	49.9 (57)
BELGIUM	140.6	75.5	101.4 (143)
BULGARIA	4.2	1.7	2.8 (3)
CZECHOSLOVAKIA	1.3	0.9	1.0 (2)
DENMARK	41.5	16.2	26.9 (20)
FED REP GERMANY	117.7	67.0	85.1 (804)
FINLAND	29.0	27.3	27.9 (16)
FRANCE	114.4	52.7	76.8 (589)
GERMAN DEM REP	8.6	2.3	4.5 (12)
GREECE	84.1	44.9	62.3 (80)
HUNGARY	5.3	0	2.1 (3)
IRELAND	18.6	0	8.4 (3)
ISRAEL	272.2	62.1	161.2 (54)
ITALY	114.5	71.6	89.5 (658)
LUXEMBOURG	250.0	137.9	183.7 (9)
NETHERLANDS	104.7	54.1	74.8 (124)
NORWAY	84.9	48.1	63.7 (39)
POLAND	0	0.5	0.3 (1)
PORTUGAL	124.7	49.2	79.1 (77)
SPAIN	107.3	54.1	75.8 (303)
SWEDEN	140.0	52.8	120.5 (165)
SWITZERLAND	102.0	53.0	72.6 (64)
UNITED KINGDOM	35.7	12.8	21.8 (185)
YUGOSLAVIA	27.2	9.9	17.2 (36)

Table V. Acceptance rate of patients aged 65 and over onto renal replacement programmes in 24 European countries in 1983. Acceptance rates for males, females and both sexes together are shown. Absolute numbers (N) are given in parentheses.

age + sex specific
acceptance rate

000005

COUNTRY	AGE SPECIFIC ACCEPTANCE RATE/10 ⁶ 1983	
	65-74	75 AND OVER
AUSTRIA	65.8	21.0
BELGIUM	134.0	50.7
BULGARIA	1.4	5.6
CZECHOSLOVAKIA	1.6	0
DENMARK	44.6	0
FED REP GERMANY	110.0	46.4
FINLAND	39.6	5.2
FRANCE	96.0	51.6
GERMAN DEM REP	6.8	1.0
GREECE	76.8	38.8
HUNGARY	3.3	0
IRELAND	8.7	7.8
ISRAEL	196.5	84.9
ITALY	111.2	49.1
LUXEMBOURG	156.3	117.6
NETHERLANDS	110.7	21.2
NORWAY	100.8	8.1
POLAND	0	0.8
PORTUGAL	86.2	63.1
SPAIN	96.4	39.1
SWEDEN	130.8	29.4
SWITZERLAND	93.3	41.9
UNITED KINGDOM	30.3	8.3
YUGOSLAVIA	22.8	5.8

(305) Total

Table VI. Age specific acceptance rates of patients onto renal replacement therapy in 1983 according to age at start of treatment, in 24 European countries.

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Trends in acceptance of elderly patients for treatment by dialysis and transplantation have been studied in more detail in five selected countries, Sweden, Italy, the United Kingdom, the Federal Republic of Germany and France (Figures 1-5). The graphs are laid out in the same way for each country. They show the ~~take-on~~ ^{acceptance} rate of new patients in the years 1974 to 1983, comparing acceptance of patients aged between 15 and 64 with that of those aged 65 and over. In each case, males and females are shown separately. As in Table V, the acceptance rates are age and sex specific. Figure 1 shows results for the Federal Republic of Germany. There has been a dramatic rise in the acceptance of elderly males for treatment over the decade and in 1978 their entry rate to renal replacement therapy exceeded that of their young counterparts. In 1982 the takeon exceeded 120 pmp compared to around 70 pmp for males aged between 15 and 64 in that year. The acceptance of

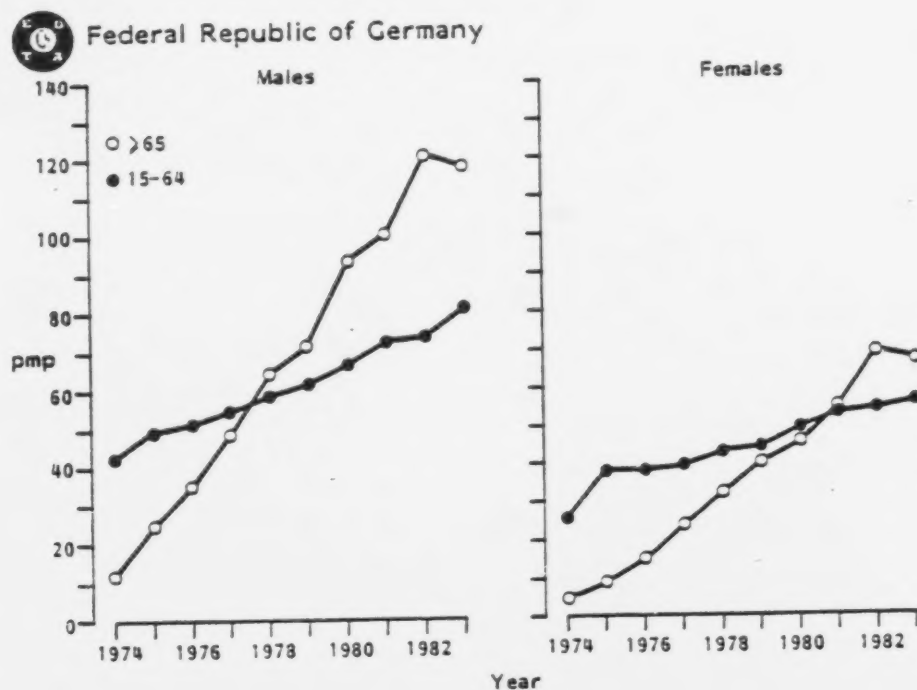


Figure 1. Age and sex specific acceptance rates onto renal replacement therapy in the Federal Republic of Germany in the years 1974-83. Males and females are shown separately according to age at start of treatment (15-64

000697

elderly females has progressed more slowly, passing that of the younger age group only in 1981. It appears that even in a country like the ^{FRG} Federal Republic which has one of the largest renal replacement programmes in Europe there may be some "triage" of patients, with elderly males preferred over elderly females in the initial stages of expansion of the programme. Figure 2 shows similar results for France. In the case of this country, the takeon of elderly males exceeded that of those aged between 15 and 64 in 1977, and for females the crossover took place correspondingly later, in 1979. Over the decade the acceptance of young patients, whether male or female, appears to have changed very little while that of the elderly has

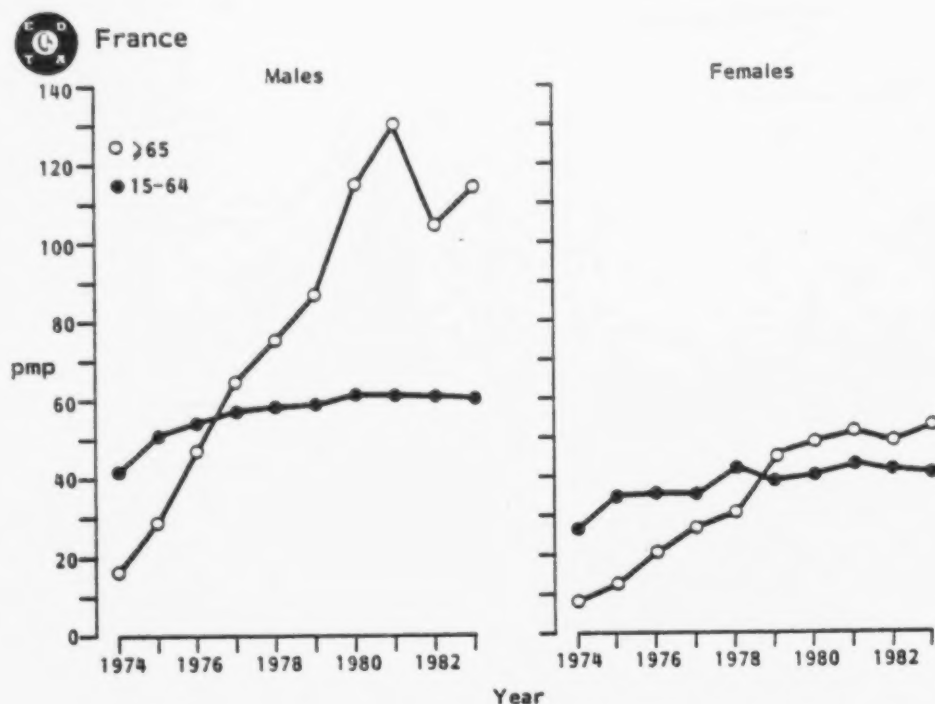


Figure 2. Age and sex specific acceptance rates onto renal replacement therapy in France in the years 1974-83. Males and females are shown separately according to age at start of treatment (15-64 years and 65 and over).

000698

continued to grow. The pattern in the United Kingdom differs markedly from the previous two. It should be noted that the scale is very much smaller because acceptance rates even for young males exceeded 50 pmp only in 1983. The limitation of services in the United Kingdom means that comparatively few elderly patients have been taken on to treatment, and the acceptance rates do not yet exceed those for the young, whether male or female.

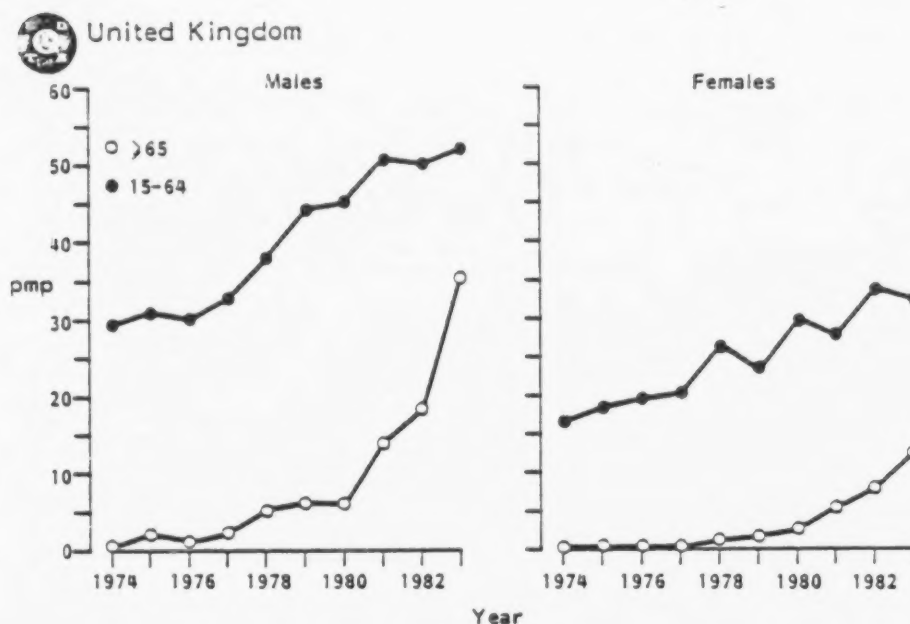


Figure 3. Age and sex specific acceptance rates onto renal replacement therapy in the United Kingdom in the years 1974-83. Males and females are shown separately according to age at start of treatment (15-64 years and 65 and over).

However, there has been a rapid increase in the takeon rate of elderly males between 1980 and 1983, and this rise has begun to show for females since 1982. The pattern in Italy is similar to that in France and the Federal Republic of Germany although the rise in acceptance of the elderly shows signs of having slowed between 1981 and 1983. Sweden (figure 5) is remarkable because the acceptance rate of elderly females does not yet

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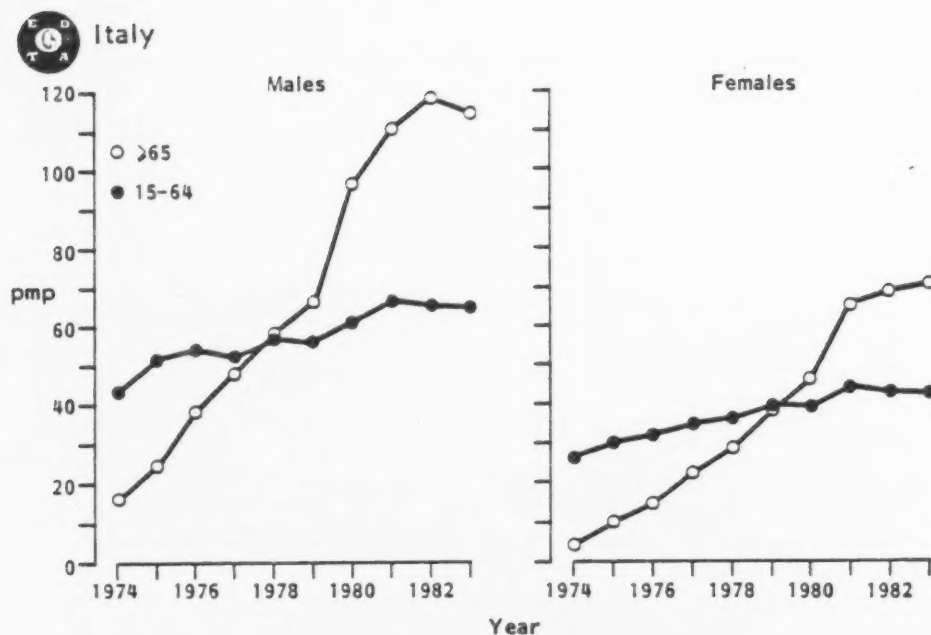


Figure 4. Age and sex specific acceptance rates onto renal replacement therapy in Italy in the years 1974-83. Males and females are shown separately according to age at start of treatment (15-64 years and 65 and over).

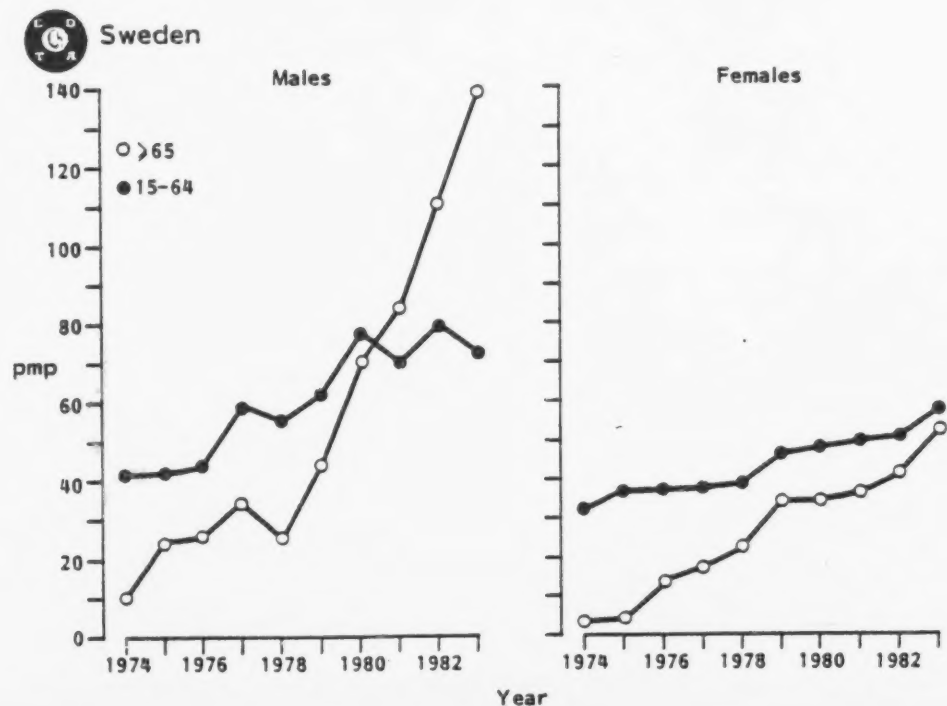


Figure 5. Age and sex specific acceptance rates onto renal replacement therapy in Sweden in the years 1974-83. Males and females are shown separately according to age at start

000700

exceed that of those aged between 15 and 64, although the takeon of elderly males had soared between 1978 and 1983. These different patterns in part reflect differences in the provision of renal services, but may also be a reflection of differences in the epidemiology of chronic renal failure in different European countries.

The total number of patients alive at the end of 1983 who commenced renal replacement therapy aged 65 and over has been analysed by country, and the results are shown in Table VII. The first column shows the numbers of these patients alive on treatment at the end of that year per million population, the second their proportion as a percentage of all live patients. The pattern is similar to that shown in acceptance rates, with a great variation between individual countries. It is important to note that in the large Western European countries, these elderly patients constitute between 10 and 20% of all patients alive on treatment at the end of 1983.

2. Primary Renal Disease

The EDTA Registry collects information on 53 separate diseases leading to ESRF. The distribution of these primary renal diseases has been analysed in young and old patients and the results are presented in Tables VIII to XIII. The diseases have been grouped for purposes of convenience as follows: chronic renal failure aetiology uncertain (CRF ?), glomerulonephritis (GN), pyelonephritis/interstitial nephritis (PN), nephropathy caused by drugs (Drug), cystic kidney disease (Cyst.), hereditary kidney disease (Hered.), renal vascular disease (Vasc.), diabetes (Diab.), multi-system disease (Multi-Sys.) and other. A full list of the diseases is shown in

COUNTRY	PER MILLION POPULATION	% LIVE PATIENTS
AUSTRIA	96.3	7.8
BELGIUM	248.2	11.5
BULGARIA	2.8	0.4
CZECHOSLOVAKIA	3.1	0.6
DENMARK	65.9	5.2
FED REP GERMANY	230.7	12.5
FINLAND	66.3	4.4
FRANCE	240.9	12.2
GERMAN DEM REP	6.0	1.0
GREECE	102.0	9.6
HUNGARY	2.8	0.9
IRELAND	25.2	2.2
ISRAEL	468.7	13.5
ITALY	241.0	12.3
LUXEMBOURG	326.5	18.2
NETHERLANDS	168.4	11.1
NORWAY	119.3	9.5
POLAND	0.8	0.3
PORTUGAL	108.8	7.4
SPAIN	158.7	6.8
SWEDEN	143.9	9.8
SWITZERLAND	208.9	10.5
UNITED KINGDOM	31.6	2.8
YUGOSLAVIA	34.8	2.9

Table VII. Stock of patients aged 65 and over at first treatment
alive on renal replacement therapy on 31 December 1983
according to country. Numbers alive per million population
where a percentage of all live patients are given

000702

the Instruction Sheet for the 1984 questionnaire which accompanies this report. The study was carried out to show the distribution of primary renal disease in six separate age and sex groups according to year of first treatment between 1974 and 1983. The age groups used are under 15, 15-64, and 65 and above at first treatment. Table VIII shows the proportional distribution of primary renal diseases in the years 1974-83 in males commencing treatment aged 15 and under. Glomerulonephritis and pyelonephritis account for almost half of these cases with a slight preponderance of glomerulonephritis over the decade. Table IX shows the same results for

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI-SYS.	OTHERS
1974	1.7	32.8	16.4	0	5.2	26.7	1.7	0	6.0	9.5
1975	2.8	22.4	24.5	0	16.1	19.6	1.4	0	7.7	5.6
1976	1.9	30.9	22.2	0	6.8	24.1	1.2	0	10.5	2.5
1977	2.7	35.8	21.6	0	6.1	21.6	0.7	0	10.8	0.7
1978	5.5	21.0	29.8	0.6	8.8	24.3	0	0.6	6.1	3.3
1979	4.0	25.9	24.1	0	11.2	25.9	0	0	6.7	2.2
1980	2.6	25.9	25.4	0	7.0	31.1	0.9	0	5.7	1.3
1981	3.8	27.8	25.7	0.4	7.2	21.5	1.3	0.8	9.3	2.1
1982	4.0	17.5	24.7	0.4	7.6	25.5	2.0	0.4	15.1	2.8
1983	4.3	23.3	23.7	1.2	6.6	21.8	2.7	0.8	8.2	7.4
ALL YRS	3.5	25.6	24.2	0.3	8.2	24.3	1.2	0.3	8.8	3.5

Table VIII. Proportional distribution of primary renal diseases in males aged under 15 at start of renal replacement therapy shown by first year of therapy 1974-83.

000002

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI-SYS.	OTHERS
1974	2.9	25.2	24.3	0.0	4.9	25.2	1.0	0.0	7.8	8.7
1975	6.6	31.4	19.8	1.7	9.9	18.2	1.7	0.0	6.6	4.1
1976	5.7	30.5	22.7	0.7	10.6	14.9	2.8	0.0	8.5	3.5
1977	3.9	29.6	30.3	0.7	9.2	13.2	1.3	0.0	8.6	3.3
1978	6.3	34.2	19.5	0.0	10.0	16.8	0.5	0.0	8.9	3.7
1979	6.7	30.3	21.8	0.0	8.5	15.2	3.0	1.2	11.5	1.8
1980	2.1	27.7	25.1	0.0	9.4	20.9	0.5	0.0	8.9	5.2
1981	11.2	26.3	18.4	1.1	7.3	21.2	1.7	0.6	9.5	2.8
1982	4.6	30.4	28.4	0.0	5.7	11.9	2.1	1.0	14.4	1.5
1983	8.1	27.1	16.7	0.9	11.3	20.4	1.4	1.8	7.2	5.0
ALL YRS	6.0	29.3	22.5	0.5	8.8	17.6	1.6	0.5	9.4	3.8

Table IX. Proportional distribution of primary renal diseases in females aged under 15 at start of renal replacement therapy shown by first year of therapy 1974-83.

girls aged under 15. The distribution of primary renal diseases does not differ greatly between the two sexes. Tables X and XI show results for males and females between 15 and 64 at first treatment respectively. Amongst the young males (Table X) glomerulonephritis accounted for almost 40% of all cases taken on for treatment in the decade up to 1983, compared to 26% for females. In contrast, pyelonephritis/interstitial nephritis accounted for almost a quarter of all primary renal disease in the young females, 15-64 compared to under 15% in the males. Chronic renal failure of unknown aetiology accounted for about 10% of cases in both groups. Amongst elderly

000704

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI-SYS.	OTHERS
1974	3.0	52.1	13.9	2.2	8.0	3.2	6.3	2.6	2.3	6.4
1975	8.2	47.7	13.4	1.9	8.1	2.8	7.2	3.6	2.1	5.0
1976	8.4	45.0	14.7	1.8	7.9	2.9	8.0	3.7	2.8	4.7
1977	9.7	41.2	15.5	1.6	8.7	2.9	8.4	4.6	3.1	4.2
1978	10.3	40.3	14.5	1.6	8.6	2.8	9.5	4.8	3.2	4.5
1979	10.4	38.6	14.6	1.7	8.7	2.4	9.1	7.0	3.6	3.8
1980	11.3	38.0	14.3	1.6	8.1	2.9	8.8	7.4	3.3	4.4
1981	11.7	35.5	14.9	1.7	8.7	2.6	9.6	7.8	3.9	3.6
1982	12.3	34.9	14.9	1.7	8.4	2.8	9.7	8.0	3.5	3.8
1983	12.9	34.5	14.8	1.6	8.5	2.0	8.8	9.5	3.6	4.0
ALL YRS	10.4	39.6	14.6	1.7	8.4	2.7	8.7	6.4	3.2	4.3

Table X. Proportional distribution of primary renal diseases in males aged 15-64 at start of renal replacement therapy shown by first year of therapy 1974-83.

patients the proportion of cases with ESRF of unknown cause is very much higher at 19.8% in males over the decade up to 1983 (Table XII) and 18% in females (Table XIII). The other interesting observation in the elderly is the frequency of pyelonephritis/interstitial nephritis as the diagnosis accounting for almost a quarter of the cases in males and a third of the cases in females over the ten year period. As would be expected, hereditary disease is an uncommon cause of chronic renal failure in this age group. The proportion of patients with ESRF due to diabetes has grown gradually over the decade and accounted for almost 10% of new cases amongst those

000795

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI SYS.	OTHERS
1974	3.1	36.0	27.3	5.8	10.8	2.8	3.6	2.0	3.0	5.6
1975	7.3	32.2	25.9	5.7	11.4	2.5	4.8	2.8	3.4	4.0
1976	8.1	31.0	26.5	5.7	11.3	2.3	5.2	3.0	3.6	3.5
1977	9.3	28.0	26.0	6.0	11.8	2.0	5.1	3.5	4.2	4.1
1978	10.0	26.4	25.7	5.1	11.3	2.5	5.8	4.6	4.7	4.0
1979	10.6	24.8	25.9	5.1	11.6	2.5	5.8	5.6	4.8	3.9
1980	10.8	25.7	23.0	6.4	11.5	2.5	5.1	6.4	5.0	3.7
1981	11.1	23.8	23.9	5.0	12.1	2.2	5.5	6.9	5.5	3.9
1982	12.5	22.8	24.6	4.9	11.4	2.2	5.9	7.5	4.9	3.2
1983	11.7	22.6	23.1	5.5	11.4	1.9	5.5	9.3	5.6	3.4
ALL YRS	10.0	26.4	24.9	5.5	11.5	2.3	5.3	5.7	4.7	3.8

Table XI. Proportional distribution of primary renal diseases in females aged 15-64 at start of renal replacement therapy shown by first year of therapy 1974-83.

aged between 15 and 64 in 1983. In elderly females the figure was 9% and in elderly males, less than 7%. This may reflect selection practice and it is known from previous work carried out by the Registry that in some countries in Europe, patients with diabetic nephropathy account for almost one in four new cases (3). It is to be expected that a growing number of elderly patients with end stage renal failure due to diabetes will be taken on in future years.

000706

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI-SYS.	OTHERS
1974	4.4	31.1	28.4	2.7	4.9	0.5	9.8	2.7	1.6	13.7
1975	13.5	29.8	24.7	2.6	4.2	0	10.9	4.5	1.3	8.7
1976	15.4	22.1	29.1	3.0	5.8	0.5	12.8	4.1	3.4	4.1
1977	17.5	18.3	28.8	3.3	5.9	0.2	13.8	3.6	3.9	4.7
1978	19.4	19.7	25.5	4.0	4.7	0.5	13.1	5.4	2.5	5.2
1979	22.3	18.1	23.8	2.3	4.6	1.0	12.5	5.3	4.6	5.5
1980	19.3	19.8	25.6	2.4	4.3	0.4	13.6	5.5	4.6	4.6
1981	22.2	16.9	24.7	2.8	4.5	0.3	13.4	6.3	5.1	4.4
1982	21.3	16.3	23.3	2.0	5.2	0.4	16.2	5.9	5.8	3.8
1983	20.3	17.2	21.4	2.3	4.6	0.4	15.9	6.9	4.6	6.5
ALL YRS	19.8	18.6	24.5	2.6	4.8	0.4	14.1	5.6	4.4	5.2

Table XII. Proportional distribution of primary renal diseases in males aged 65 and over at start of renal replacement therapy shown by first year of therapy 1974-83.

000707

YEAR	PRIMARY RENAL DISEASE %									
	CRF ?	GN	PN	DRUG	CYST.	HERED.	VASC.	DIAB.	MULTI-SYS.	OTHERS
1974	3.4	22.0	37.3	5.9	7.6	0.0	11.9	1.7	3.4	6.8
1975	13.5	19.8	33.9	5.7	7.3	1.6	7.3	3.6	1.0	6.3
1976	15.4	13.8	34.3	7.4	7.1	1.6	9.6	3.2	3.8	3.8
1977	16.6	11.3	34.8	8.9	8.6	0.9	9.3	3.5	2.7	3.3
1978	17.3	13.2	35.2	6.9	7.9	0.9	9.5	4.4	2.6	2.1
1979	19.2	11.7	33.2	6.8	6.4	0.6	8.7	6.8	3.5	3.0
1980	17.5	13.1	29.4	7.6	7.7	0.6	8.5	7.2	5.4	3.0
1981	20.2	11.9	27.7	7.7	6.4	0.8	9.8	9.1	3.9	2.6
1982	17.8	11.2	30.2	7.8	7.4	0.7	10.8	7.2	4.7	2.2
1983	19.1	12.9	25.3	8.0	7.2	0.5	10.6	9.0	3.9	3.6
ALL YRS	18.0	12.6	30.1	7.6	7.2	0.7	9.8	7.0	3.9	3.0

Table XIII. Proportional distribution of primary renal diseases in females aged 65 and over at start of renal replacement therapy shown by first year of therapy 1974-83.

3. Choice of Therapy

renal replacement therapy

The first method of therapy used to treat patients accepted for (RRT) aged 65 and above in the years 1974 - 83 has been analysed for the whole of Europe. The proportional distribution of elderly patients between first methods of treatment is shown (as a percentage) by year of first therapy in Table XIV. Hospital haemodialysis (Hosp HD) accounts for the first treatment of the vast majority of these patients while home haemodialysis (Home HD) plays only a very small part. The contribution of intermittent peritoneal dialysis (IPD) has declined between 1974 and 1983 when it accounted for only 9.5% of first treatment. In contrast, the use of continuous ambulatory peritoneal dialysis (CAPD) has grown and accounted for 12.1% of first treatment in 1983. Grafting is seldom used as a first method of treatment for these patients. Choice of first therapy does not differ greatly between patients aged 65-74 at first treatment and those aged 75 and above.

YEAR	HOSP HD	HOME HD	IPD	CAPD	GRAFT
1974	80.2	0.6	18.8	0.0	0.3
1975	80.5	0.2	19.0	0.0	0.4
1976	81.4	0.2	18.0	0.0	0.4
1977	83.8	0.0	16.0	0.0	0.3
1978	81.1	0.1	18.5	0.1	0.1
1979	77.6	0.1	20.6	1.4	0.3
1980	73.2	0.1	13.8	12.6	0.2
1981	74.5	0.1	12.9	12.4	0.2
1982	75.5	0.1	10.9	13.3	0.1
1983	78.1	0.2	9.5	12.1	0.1

Table XIV. Proportional distribution (percentage) of first method of therapy amongst patients commencing renal replacement therapy aged 65 and over according to year of first treatment

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Table XV shows the results of a study of first method of treatment for elderly patients in individual countries in 1983. Practice varies greatly.

COUNTRY (N)	HOSP HD	HOME HD	IPD	CAPD	GRAFT
AUSTRIA (57)	100.0	0.0	0.0	0.0	0.0
BELGIUM (139)	84.9	0.0	0.0	15.1	0.0
BULGARIA (3)	100.0	0.0	0.0	0.0	0.0
CZECHOSLOVAKIA (2)	50.0	0.0	50.0	0.0	0.0
DENMARK (17)	11.8	0.0	58.8	29.4	0.0
EGYPT (20)	100.0	0.0	0.0	0.0	0.0
FED REP GERMANY (777)	93.6	0.3	4.8	1.4	0.0
FINLAND (16)	37.5	0.0	12.5	50.0	0.0
FRANCE (552)	72.1	0.2	10.1	17.6	0.0
GERMAN DEM REP (12)	100.0	0.0	0.0	0.0	0.0
GREECE (62)	82.3	0.0	3.2	14.5	0.0
HUNGARY (3)	66.7	0.0	33.3	0.0	0.0
IRELAND (3)	0.0	0.0	0.0	100.0	0.0
ISRAEL (53)	54.7	1.9	35.8	7.5	0.0
ITALY (601)	74.2	0.0	9.2	16.5	0.2
LUXEMBOURG (10)	100.0	0.0	0.0	0.0	0.0
NETHERLANDS (123)	84.6	0.0	0.0	14.6	0.8
NORWAY (34)	88.2	0.0	11.8	0.0	0.0
POLAND (1)	0.0	0.0	100.0	0.0	0.0
PORTUGAL (71)	98.6	0.0	1.4	0.0	0.0
SPAIN (257)	72.4	0.4	14.8	12.1	0.4
SWEDEN (116)	64.7	0.0	26.7	8.6	0.0
SWITZERLAND (62)	87.1	0.0	1.6	11.3	0.0
TUNISIA (1)	100.0	0.0	0.0	0.0	0.0
TURKEY (8)	100.0	0.0	0.0	0.0	0.0
UNITED KINGDOM (171)	38.0	0.0	25.1	36.8	0.0
YUGOSLAVIA (31)	90.3	0.0	9.7	0.0	0.0

Table XV. Proportional distribution (percentage) of first method of therapy amongst patients commencing renal replacement therapy in 1983 aged 65 and over by country. Absolute numbers of patients (N) are given in parentheses.

In the United Kingdom, continuous ambulatory peritoneal dialysis was used almost as often as hospital haemodialysis. In the Federal Republic of Germany by contrast over 90% of 777 elderly patients commencing treatment in 1983 were started on hospital haemodialysis. In Belgium, Greece, the Netherlands, Norway, Portugal, Switzerland and Yugoslavia, the figure exceeded 80%. It is clear that hospital haemodialysis is still the most popular first method of treatment for elderly patients. There are signs, however, that CAPD may come to play a greater role in the future, particularly where resources are scarce.

4. Balance of Therapies

A new method for analysing balance of therapies for individual groups of patients devised by Dr. Neville Selwood (4) has been used to look at treatment of elderly patients. The analysis shows the proportional contribution of therapies to the treatment of a defined group of subjects at different intervals after start of first treatment. The Selwood Method has been used to look at the proportional contribution of different modes of therapy to the treatment of elderly patients commencing treatment in two years, 1974 and 1979. Table XVI shows the results for the cohort of patients commencing treatment in 1974. The contribution of four methods of treatment to the care of elderly patients with ESRF is shown at start of therapy and one, two, three, four and five years later. CAPD is not included as it was not used for these patients over this interval. The results show that for patients commencing treatment in 1974, the contribution of hospital haemodialysis increased gradually to account for the care of almost 92% of elderly patients still alive five years after first treatment. Similarly,

000728

METHOD OF TREATMENT	PROPORTIONAL CONTRIBUTION OF THERAPIES %					
	START RRT	1 YR	2 YR	3 YR	4 YR	5 YR
HOSPITAL HAEMODIALYSIS	80.0	89.6	89.9	90.5	91.8	91.8
HOME HAEMODIALYSIS	0.7	3.1	3.9	5.4	4.5	6.2
IPD	19.0	6.9	5.3	2.4	1.5	0
GRAFT	0.3	0.4	0.9	1.8	2.2	2.1

Table XVI. Proportional contribution of therapies (as a percent) to the treatment of patients commencing renal replacement therapy in 1974 aged 65 and over. Contribution of the therapies is shown at start of treatment, one, two, three, four and five years later.

the proportional contribution of home haemodialysis grew, but this accounts for only a small proportion of care. Grafting did not appear to be of great importance even five years after start of first treatment, and the contribution of IPD declined rapidly after the first year of therapy. Table XVII shows the results of the same analysis carried out for a cohort of elderly

METHOD OF TREATMENT	PROPORTIONAL CONTRIBUTION OF THERAPIES %					
	START RRT	1 YR	2 YR	3 YR	4 YR	5 YR
HOSPITAL HAEMODIALYSIS	77.3	79.7	81.5	82.6	85.1	89.1
HOME HAEMODIALYSIS	0.1	2.2	2.5	3.1	3.3	2.7
IPD	20.8	13.0	9.9	6.1	3.9	1.6
CAPD	1.5	4.1	4.7	6.3	5.3	4.3
GRAFT	0.3	0.9	1.5	1.9	2.3	2.3

Table XVII. Proportional contribution of therapies (as a percent) to the treatment of patients commencing renal replacement therapy in 1979 aged 65 and over. Contribution of the therapies is shown at start of treatment, one, two, three,

patients commencing treatment in 1979. Although the proportional contribution of hospital haemodialysis has declined compared to the previous group of patients it remains the most important form of therapy in elderly patients and as before its use increased over 5 years. Home haemodialysis appeared to be even less important than previously while the pattern of grafting has not changed. The interesting development is the use of continuous ambulatory peritoneal dialysis (CAPD) which has latterly developed as a treatment option. However, it accounted for less than 5% of treatment for elderly patients still alive five years after first therapy in 1979. The evolution of treatment of the elderly after first RRT does not appear to have changed greatly for patients starting in 1979 compared to those starting in 1974. At every interval after first therapy, hospital haemodialysis dominated the treatment profile.

For comparison, Table XVIII shows the proportional contribution of therapies to treatment of patients who commenced in 1979, irrespective of age.

METHOD OF TREATMENT	PROPORTIONAL CONTRIBUTION OF THERAPIES %					
	START RRT	1 YR	2 YR	3 YR	4 YR	5 YR
HOSPITAL HAEMODIALYSIS	82.5	77.1	70.9	67.8	65.1	63.3
HOME HAEMODIALYSIS	0.2	7.8	9.5	10.0	9.8	9.4
IPD	15.7	5.3	3.7	1.9	1.2	0.7
CAPD	0.6	2.6	3.2	3.4	3.2	2.9
GRAFT	1.0	7.3	12.7	16.9	20.7	23.7

Table XVIII. Proportional contribution of therapies to the treatment of patients commencing renal replacement therapy in 1979

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5. Causes of Death in Elderly Patients on Renal Replacement Therapy

The causes of death in patients aged 65 and over at start of treatment who commenced therapy between 1974 and 1983 have been analysed, together with those for all ages. The results, shown in Tables XIX and XX are given according to the year in which the patients commenced therapy. For each cohort the number of patients who have died is given together with the proportion of deaths due to different causes. These have been grouped as follows: Cause of death uncertain (?), Cardiac, Vascular, Infection, Liver disease (Liver), Social, Accident and Other identified causes. A copy of the instruction sheet which accompanied the

YEAR 1st RRT (N)	CAUSE OF DEATH (%)							
	?	CARDIAC	VASCULAR	INFECTION	LIVER	SOCIAL	ACCIDENT	OTHER
1974 (264)	0.8	44.3	16.7	9.1	3.0	3.4	0	22.7
1975 (426)	1.2	38.5	20.2	12.4	1.6	3.5	0	22.6
1976 (642)	1.7	35.5	20.6	11.7	2.3	3.7	0.2	24.3
1977 (886)	2.7	38.0	16.9	11.4	2.4	3.6	0.2	24.8
1978 (1096)	4.0	37.7	17.6	11.2	2.2	4.4	0.1	22.8
1979 (1311)	4.4	40.3	16.1	11.6	1.9	3.7	0.2	21.8
1980 (1533)	6.9	37.5	15.4	11.9	2.5	3.7	0.5	21.6
1981 (1477)	5.7	37.8	16.0	12.5	1.3	4.5	0.4	21.8
1982 (1304)	6.1	35.2	16.0	13.7	1.5	4.1	0.8	22.6
1983 (935)	7.9	38.5	15.7	9.3	1.2	5.3	0.9	21.2

Table XIX. Proportional distribution of causes of death in patients commencing RRT aged 65 years and over according to year of first therapy, 1974-83. Number of deaths (N) also shown.

000714

YEAR 1ST RRT (N)	CAUSE OF DEATH (%)							
	?	CARDIAC	VASC.	INFE.	LIVER	SOCIAL	ACC.	OTHER
1974 (4,611)	1.2	38.9	18.5	17.1	2.6	2.6	0.1	19.0
1975 (5,204)	1.6	40.8	17.8	15.0	2.9	2.2	0.2	19.5
1976 (5,170)	1.9	40.5	17.2	15.6	3.0	2.5	0.2	19.1
1977 (5,550)	2.5	39.8	18.3	14.6	3.2	2.6	0.4	18.6
1978 (5,909)	3.8	39.5	17.5	14.9	2.7	2.6	0.4	18.6
1979 (5,863)	4.1	40.3	16.9	15.6	2.3	2.9	0.4	17.5
1980 (5,832)	5.5	39.4	16.4	14.8	2.5	3.1	0.8	17.5
1981 (5,312)	5.0	41.6	16.5	14.5	1.9	3.2	0.8	16.5
1982 (4,424)	5.5	38.4	16.3	15.0	2.8	3.3	1.2	17.5
1983 (3,035)	6.6	41.7	15.8	12.0	1.7	3.6	0.8	17.8

Table XX. Proportional distribution of causes of death in patients according to year of first renal replacement therapy 1974-83. Number of deaths (N) also shown.

000711

1983 questionnaire is appended to this report to show the detailed listing of causes under each of these broad headings. Cardiac causes account for the majority of deaths. A more detailed analysis of causes of death in 9,862 elderly patients who commenced treatment between 1974 and 1983 is shown in Table XXI. Here, the individual causes of death are given separately. Myocardial ischaemia and infarction and cerebrovascular accidents account for almost 25% of mortality. Other cardiac causes account for a further 20%. Cachexia is the leading cause of non-cardiovascular death amongst the elderly accounting for 7.9% of the 9,862 deaths.

CAUSE OF DEATH (N=9862)	%
MYOCARDIAL ISCHAEMIA AND INFARCTION	12.4
CEREBROVASCULAR ACCIDENT	12.0
OTHER CARDIAC FAILURE	10.2
CARDIAC ARREST, CAUSE UNKNOWN	10.0
CACHEXIA	7.9
MALIGNANT DISEASE	6.3
SEPTICAEMIA	4.9
CAUSE OF DEATH UNCERTAIN/NOT DETERMINED	4.9
PULMONARY BACTERIAL INFECTION	3.5
TOTAL	72.1

Table XXI. Proportional distribution of nine leading causes of death in patients aged 65 years and over at first therapy commencing in 1974-83.

000716

6. Survival of Elderly Patients on Renal Replacement Therapy

Figure 6 shows overall survival of patients who commenced treatment between 1974 and 1983, aged 65 and over, on renal replacement therapy. At one year the survival figure was 76% compared to 56% at two years and 23% at five years. These figures apply to all patients commencing between 1974 and 1983, and the numbers at risk at the start of each interval are diminished not only by those who have died, but also by those who have been removed from the analysis as not being at risk of death because of insufficient years on renal replacement therapy.

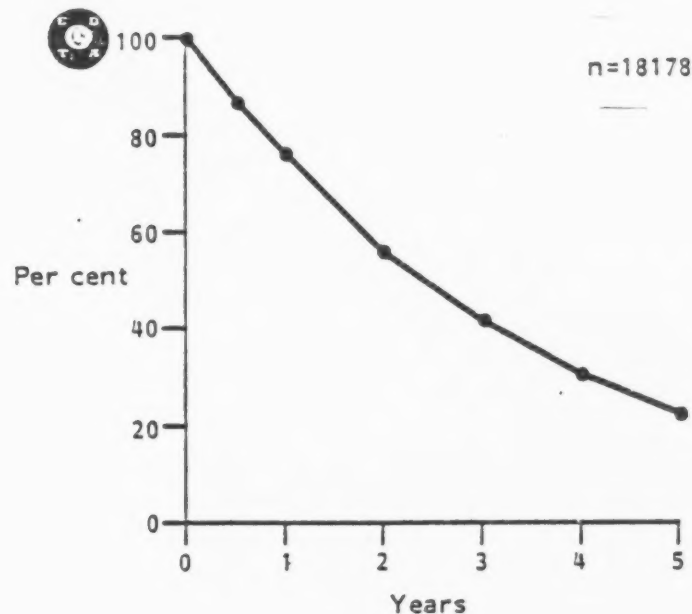


Figure 6. Survival of elderly patients commencing treatment between 1974 and 1983 on all forms of renal replacement therapy

010-17

Survival of elderly patients on different forms of treatment have been analysed and the results are shown in figures 7, 8 and 9. Survival has been calculated in such a way that change of therapy from that under consideration is treated as lost to follow up for the calculation. Figure 7 shows survival of patients on first haemodialysis. This includes 15,051 elderly subjects commencing treatment between 1974 and 1983 who had haemodialysis at some time. The one year survival in this group was 78% compared to just under 35% at four years. Survival figures become less reliable as the interval after the specified therapy increases because the numbers at risk diminish rapidly. At five years, there were 1,626 patients

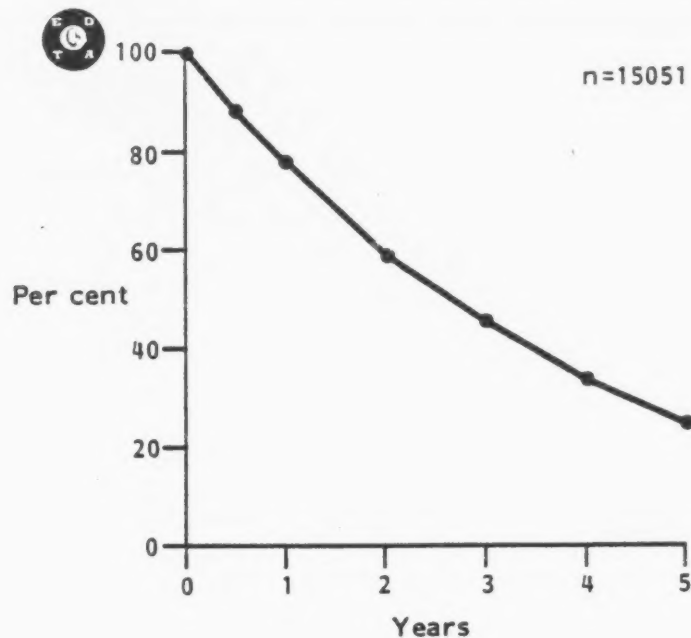


Figure 7. Survival of elderly patients commencing treatment between 1974 and 1983 on first haemodialysis

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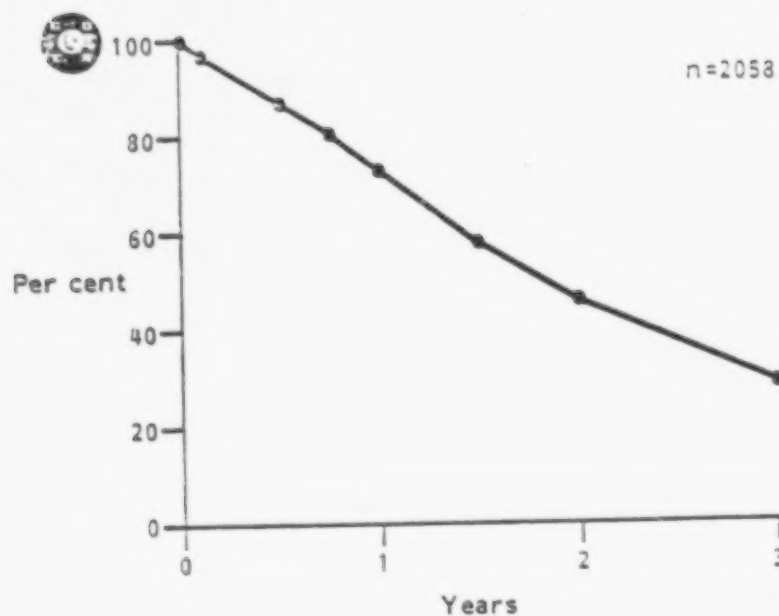


Figure 8. Survival of elderly patients commencing treatment between 1974 and 1983 on CAPD

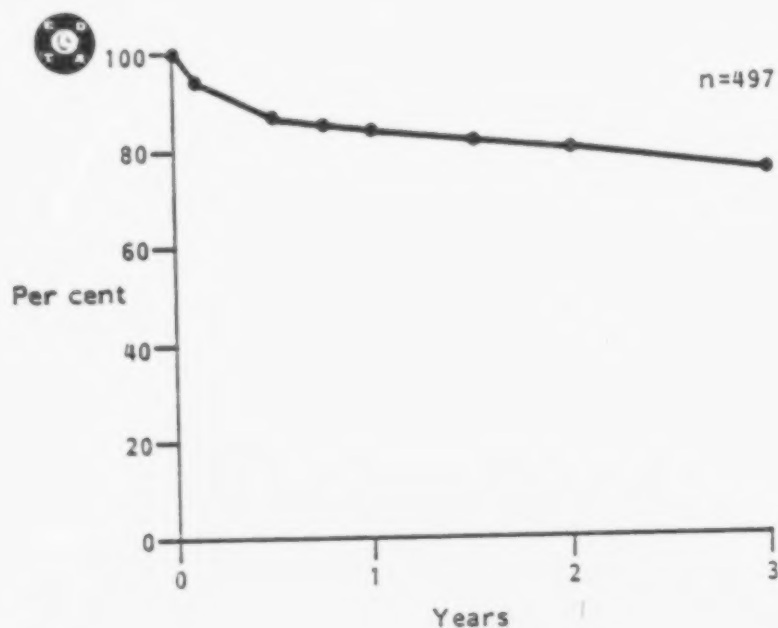


Figure 9. Survival of elderly patients commencing treatment between 1974 and 1983 with first graft

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still at risk of dying on first haemodialysis. The 15,051 original patients have been diminished by death, changes of treatment and removal of patients who have not been on treatment for five years. For this reason, the results in figures 8 and 9 have only been shown to three years. Figure 8 shows survival of elderly patients on CAPD. The three year survival figure was just over 38%. The three year survival of elderly patients with a first graft was 75% (figure 9). However, of the 497 elderly patients ever grafted, only 178 were still at risk at the beginning of the three year interval. Patients whose grafts had failed in the interval up to three years were treated as lost to observation.

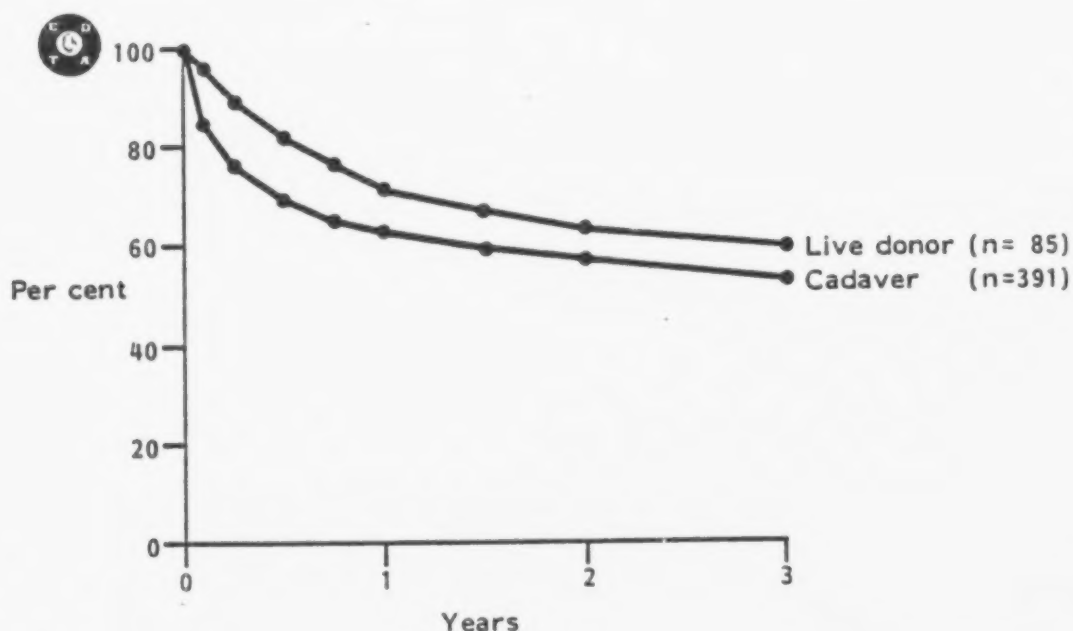


Figure 10. First graft survival in elderly patients commencing treatment between 1974 and 1983, according to source

Figure 10 shows the graft survival rather than patient survival in elderly subjects according to source of transplant. Amongst these patients commencing treatment between 1974 and 1983, 85 have received live donor grafts and 391 cadaver grafts. For the purpose of this analysis, death with a functioning transplant is treated as graft failure.

Table XXII shows overall survival after first renal replacement therapy according to age at first treatment in three age groups. Changes of therapy are ignored in the calculation of overall survival. This is not the case for survival on named treatments shown in the same table, where changes of therapy are treated as lost to follow-up in the calculation. Where numbers are small, for example patients grafted over the age of 65, great care must be exercised in interpreting the results.

It is dangerous to compare survival on different modes of therapy or for different age groups. The Registry collects data on only a limited number of variables, and the variation in survival observed may be due to preselection of patients; for example an 85% survival at one year after grafting for patients aged 75 and over at first renal replacement therapy probably reflects very careful patient selection.

7. Peritonitis in Elderly Patients on CAPD

Peritonitis is a frequent complication of treatment by continuous ambulatory peritoneal dialysis. The incidence of this complication amongst elderly patients has been calculated for the years 1981 to 1983. The results include all patients who commenced treatment between 1974 and 1983. The

MODE OF THERAPY	AGE AT FIRST RRT	SAMPLE SIZE	PATIENT SURVIVAL %		
			1 YR	2 YR	3 YR
AFTER FIRST RRT	<65	>100,000	88.1 ± 0.7	78.3 ± 1.0	70.3 ± 1.2
	65-74	15,423	76.9 ± 1.9	57.5 ± 2.4	43.4 ± 2.6
	≥75	2,866	69.8 ± 3.4	48.5 ± 4.0	34.8 ± 4.1
	ALL	>100,000	86.5 ± 0.8	75.5 ± 1.1	67.0 ± 1.2
FIRST HAEMODIALYSIS	<65	>100,000	89.6 ± 0.8	80.3 ± 1.2	72.2 ± 1.4
	65-74	13,084	79.5 ± 2.0	61.4 ± 2.8	47.7 ± 3.0
	≥75	2,065	70.3 ± 4.0	48.0 ± 5.0	31.7 ± 4.8
	ALL	>100,000	88.3 ± 0.8	77.8 ± 1.2	69.0 ± 1.4
FIRST CAPD	<65	8,956	81.9 ± 2.1	69.7 ± 2.9	58.0 ± 3.8
	65-74	1,710	65.3 ± 4.6	46.8 ± 5.0	30.3 ± 5.4
	≥75	348	64.3 ± 6.8	34.0 ± 7.9	*****
	ALL	11,014	78.6 ± 2.2	64.5 ± 2.9	51.3 ± 3.8
FIRST GRAFT	<65	29,474	86.5 ± 1.2	81.5 ± 1.3	77.5 ± 1.5
	65-74	140	70.3 ± 7.3	61.4 ± 7.6	55.6 ± 7.8
	≥75	362	85.5 ± 3.7	79.4 ± 4.2	75.2 ± 4.7
	ALL	29,976	86.4 ± 1.2	81.3 ± 1.3	77.4 ± 1.4

Table XXII. Survival on different modes of therapy, patients commencing treatment 1974-83, according to age at start. (***** denotes <30 patients at risk.)

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incidence of peritonitis does not appear to have changed greatly over the three years and is around 1.7 episodes per patient year of treatment.

YEAR	EPISODES/PATIENT YEAR
1981	1.6
1982	1.7
1983	1.7

Table XXIII. Frequency of peritonitis in patients on CAPD who commenced treatment 1974-83 aged 65 and over

In the past, the Registry has collected information on causes of abandonment of CAPD. In 1982, 114 patients aged 65 and above at first treatment commencing therapy between 1974 and 1983 abandoned CAPD. The most common cause was peritonitis followed by inability of the patient to cope with the treatment. In the following year, 67 elderly patients abandoned CAPD and once more, peritonitis was the leading cause (Table XXIV). However, inability to cope was the cause of abandonment in only 6% of cases. CAPD was terminated at family's request in 3% of patients compared to just over 6.1% in 1982.

CAUSE	1982 % (N=114)	1983 % (N=67)
PERITONITIS	39.5	50.7
OTHER ABDOMINAL COMPLICATIONS	11.4	14.9
INADEQUATE DIALYSIS	14.0	13.4
PATIENT UNABLE TO COPE WITH CAPD	16.7	6.0
PATIENT'S REQUEST	7.9	6.0
FAMILY'S REQUEST	6.1	3.0
OTHER COMPLICATIONS RELATED TO CAPD	4.4	6.0

Table XXIV. Causes of abandonment of CAPD in patients commencing treatment 1974-83 aged 65 years and over.

000733

Acknowledgements

We thank all the doctors and their staff who have completed questionnaires. Financial contributions from national governments and commercial companies are fully acknowledged in the Combined Reports on Regular Dialysis and Transplantation in Europe, published in the Proceedings of the EDTA - ERA.

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Pitman, London

E.D.T.A. REGISTRY CENTRE QUESTIONNAIRE, 1984

Name and Address of Unit, Hospital or Institution

000725

Identification Code

1				
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To be completed by ALL CENTRES

1. In which language would you prefer to receive your feedback information? Record '1' for English, '2' for French, '3' for German, '4' for Italian or '5' for Spanish.

5	
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2. Give date on which your centre started the first patient on HAEMODIALYSIS for end stage renal failure.

month	year
6	

3. Give date on which your centre started the first patient on INTERMITTENT PERITONEAL DIALYSIS (IPD) for end stage renal failure.

10	
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4. Give date on which your centre started the first patient on CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD) for end stage renal failure.

14	
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5. Give date on which your centre started the first patient on HAEMOFILTRATION for end stage renal failure.

18	
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6. Give date on which the first TRANSPLANT OPERATION was performed IN YOUR CENTRE (excluding patients transplanted in other centres).

22	
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7. Give total number of new patients with end stage renal failure who received their first renal replacement therapy (including transplantation) in 1984 in your centre (DO NOT INCLUDE patients who commenced their treatment in another centre).

26	
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8. On 31st December, 1984 how many of all your patients were alive on the following methods of haemodialysis (HD) / haemofiltration (HF):

Hospital HD / HF (including limited/self care) 29

Home HD / HF 32

How many of these patients were on the following treatments on 31st December, 1984:

Bicarbonate HD 35 Haemofiltration 37 Haemodiafiltration 39

9. On 31st December, 1984 how many of all your patients were alive on the following methods of peritoneal dialysis (PD):

Intermittent PD 41 Continuous PD 44

How many of these patients were on the following treatments on 31st December, 1984:

Continuous cycling PD (CCPD) 47 PD combined with HD 49

10. On 31st December, 1984 how many patients on dialysis, under the care of your centre, were on a waiting list for a cadaver transplant.

51	
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11. Give total number of patients with acute (reversible) renal failure, who required renal replacement therapy, in whose care your centre was involved during 1984 (excluding post transplantation acute renal failure).

54	
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How many of these patients were treated by:

Intermittent haemodialysis 57 as only treatment combined with other treatment(s)

Intermittent haemofiltration 63

Continuous arterio-venous or veno-venous haemofiltration 69

Intermittent peritoneal dialysis 75

Continuous peritoneal dialysis 81

Plasmapheresis 87

12. Record the number of patients in whom a subclavian catheter(s) was used for haemodialysis / haemofiltration on 31st December, 1984:

used for up to 3 months 93 used for more than 3 months 95

13. In how many patients, either live or dead, ever treated by renal replacement therapy, has sclerosing peritonitis been diagnosed by your centre. (If none, enter '00').

97	
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14. Record total number of paraplegics or quadriplegics ever accepted for their first renal replacement therapy in your centre. (If none, enter '00').

99	
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15. Computerization of dialysis/transplant patient data
- Does your centre have access to computing facilities? Enter '1' for no access, '2' for dedicated computer (used only by renal/transplant unit), '3' for shared use of local hospital/university computer, '4' for use of bureau (commercial) computer or '5' for other computing facilities.
 - Describe present capability for computerized data transmission. Enter '1' for not planned, '2' for undecided, '3' for planned, '4' for under development, '5' for developed but not in use or '6' for in use.
 - Record preferred method for computerized data transmission. Enter '1' for direct telecommunications, '2' for magnetic tape, '3' for cassette, '4' for hard disc, '5' for floppy disc, '6' for computer-completed forms or '7' for other.
16. Record number of NEW CASES (including serological evidence of new disease) of hepatitis in patients and staff (including clinical and laboratory workers) in 1984:
- | | | | | | | | | | |
|------------|-------------|-----|----------------------|-------------|-----|----------------------|-----------------------|-----|----------------------|
| - Patients | Hepatitis B | 104 | <input type="text"/> | Hepatitis A | 106 | <input type="text"/> | Hepatitis non-A-non-B | 108 | <input type="text"/> |
| - Staff | Hepatitis B | 110 | <input type="text"/> | Hepatitis A | 112 | <input type="text"/> | Hepatitis non-A-non-B | 114 | <input type="text"/> |
17. If any member of staff has died from hepatitis B during 1984, record the TOTAL NUMBER in box. If no staff died enter '00'.
18. Record number of LIVE BABIES born in 1984 to:
- | | | | | | |
|-------------------|-----|----------------------|-------------------------------------|-----|----------------------|
| Women on dialysis | 118 | <input type="text"/> | Women with a functioning transplant | 120 | <input type="text"/> |
|-------------------|-----|----------------------|-------------------------------------|-----|----------------------|
19. Did you have any children aged less than 15 years on treatment during 1984? Record '1' for yes or '2' for no. If the answer is 'yes' ('1'), please answer section on 'Paediatric Information' (questions 30-33).
20. Will you provide dialysis facilities to temporary visitors (including holiday)? Record '1' for yes, '2' for no.

TRANSPLANT INFORMATION To be completed by all transplant centres

- | | Cadaver donors | Living donors |
|--|--------------------------|----------------------|
| 21. a) How many transplant operations were performed IN YOUR CENTRE in 1984? (Exclude patients transplanted in other centres). | 124 <input type="text"/> | <input type="text"/> |
| b) How many of these transplant operations were first grafts? | 130 <input type="text"/> | <input type="text"/> |
| c) How many of these transplant operations were performed on patients aged less than 15 years at time of transplant? | 136 <input type="text"/> | <input type="text"/> |
| 22. Give TOTAL number of transplant operations performed in your centre in ALL years combined to 31st December, 1984. | 142 <input type="text"/> | <input type="text"/> |
| 23. How many of the grafts ever performed in your centre were functioning on 31st December, 1984? | 146 <input type="text"/> | <input type="text"/> |
| 24. Did your centre use cyclosporin for prophylactic immunosuppression in 1984? Record '1' for yes or '2' for no.
If the answer to question 24 is yes, answer questions 25 to 29. If the answer to question 24 is no, pass directly to question 30. | 149 <input type="text"/> | <input type="text"/> |
| 25. Give date cyclosporin first used: | 150 <input type="text"/> | <input type="text"/> |
| 26. Record regimen most commonly used for prophylactic immunosuppression during first week after transplantation in 1984. Record '1' for cyclosporin alone, '2' for cyclosporin + steroids, '3' for cyclosporin + azathioprine, '4' for cyclosporin + ALG/ATG, '5' for cyclosporin + steroids + azathioprine, '6' for cyclosporin + steroids + ALG/ATG, '7' for cyclosporin + steroids + azathioprine + ALG/ATG or '8' for cyclosporin + other regime. | 154 <input type="text"/> | <input type="text"/> |
| 27. Record oral dose of cyclosporin most commonly used for prophylactic immunosuppression during first week after transplantation in 1984. (mg/kg/day) | 155 <input type="text"/> | <input type="text"/> |
| 28. Record oral maintenance dose of cyclosporin most commonly used one year after transplantation during 1984. (mg/kg/day) | 157 <input type="text"/> | <input type="text"/> |
| 29. If you used cyclosporin for prophylactic immunosuppression, did you transplant patients in 1984 who had never received a blood transfusion. Record '1' for yes or '2' for no. | 159 <input type="text"/> | <input type="text"/> |

PAEDIATRIC INFORMATION To be completed by all centres with children aged less than 15 years on treatment during 1984.

30. Is your centre a specialized dialysis centre for paediatric patients? Record '1' for yes, '2' for no.
31. Give total number of new patients aged less than 15 years with end stage renal failure who received their first renal replacement therapy (including transplantation) in 1984 in your centre (DO NOT INCLUDE patients who commenced their treatment in another centre).
- How many of these patients came from foreign countries?
32. Record number of patients in your centre aged less than 15 on 31st December, 1984 who were alive on that date on any form of dialysis/haemofiltration (including peritoneal dialysis).
33. Record number of patients on regular dialysis/haemofiltration (including peritoneal dialysis) in your centre who received a transplant at age less than 15 during 1984, either in your centre or elsewhere.

Please complete this form and return with patient questionnaires to:
Dr A Ving COITR Registry, St Thomas' Hospital, London SE1 7EH, United Kingdom

PLEASE READ INSTRUCTION SHEET AND WRITE CLEARLY, ESPECIALLY 2,4,7&9
E.D.T.A. - DIALYSIS AND TRANSPLANT REGISTRY

Name and Address of Unit, Hospital or Institution

Identification (leave blank)

000227

1. Patient's name

11

New Patients: please record family name first, followed by given name(s)

2. Sex Please record in box '1' for male

'2' for female

3. Date of Birth

31
 Day Month Year
 32

4. Primary renal disease

Record code from list corresponding to the disease

38

Further specification of primary renal disease

5. Patient transferred DURING 1984 BETWEEN DIALYSIS/TRANSPLANT CENTRES (excluding transient/holiday dialysis)

a) Did this patient COME TO your centre DURING 1984 from another dialysis/transplant centre? IF YES, enter code or address of OTHER centre and give date of arrival into your centre during 1984 AND record 'T' and date of arrival in question 6

patient came from or
 CENTRE CODE 40

Doctor Hospital

Street City & Country

Give date

b) Did you SEND this patient DURING 1984 to another dialysis/transplant centre? IF YES, enter code or address of OTHER centre and give date of departure from your centre during 1984 AND record code 'R' and date of departure in question 6

patient sent to or
 CENTRE CODE 44

Doctor Hospital

Street City & Country

Give date

6. Course of treatment and transfers.

ATTENTION! Treatment and transfer codes: see Instruction Sheet

Method of treatment
 fill in code from list

Date

Method of treatment
 fill in code from list

Date

	Day	Month	Year
48 ☐ 1st treatment (or arrival from another dialysis/transplant centre)			
55 ☐ 1st change			
62 ☐ 2nd change			
69 ☐ 3rd change			
76 ☐ 4th change			
83 ☐ 5th change			
90 ☐ 6th change			
97 ☐ 7th change			
104 ☐ 8th change			
111 ☐ 9th change			

	Day	Month	Year
118 ☐ 10th change			
125 ☐ 11th change			
132 ☐ 12th change			
139 ☐ 13th change			
146 ☐ 14th change			
153 ☐ 15th change			
160 ☐ 16th change			
167 ☐ 17th change			
174 ☐ 18th change			
181 ☐ 19th change			

For patients who have died

7. a) If patient was not alive on 1st January, 1985 give date of death

188

b) Record code from list corresponding to main cause of death

194

If '99' - specify

c) Was a transplanted kidney functioning up to time of death? If yes record '1' in box
 If no record '2' in box

198

For patients who have been transplanted

8. For question 8a, b and c record number according to codes in Instruction Sheet

	1st graft	2nd graft	3rd graft	4th graft	5th graft	6th graft
a) Source of donor kidney	197					
b) Use of cyclosporin	202					
c) Cause of graft failure	207					

9. Serum creatinine level at end of 1984. Enter code from Instruction Sheet

212

For patients on haemodialysis (HD) or haemofiltration (HF) AT ANY TIME DURING 1984

10. a) How many TIMES per week was this patient treated with HD or HF?

213

b) How many HOURS per week was this patient treated with HD or HF?

214

c) Which TYPE of haemodialyser or haemofilter was most frequently used for this patient? Enter code from this year's Instruction Sheet

216

d) How many TIMES on average was this haemodialyser or haemofilter re-used? Enter '0' for no re-use, '1' for one re-use, '2' for two re-uses and '9' for nine or more times.

219

11. Did this patient's weight gain between HD/HF treatments exceed 4kg (or 8% of body weight for patients aged less than 15 years) at least once a week during 1984? Enter '1' for yes or '2' for no

220

For patients on continuous ambulatory peritoneal dialysis (CAPD) AT ANY TIME DURING 1984

12. How many episodes of peritonitis occurred in this patient while treated by CAPD during 1984? If none, enter '00'

221

13. If this patient abandoned CAPD during 1984 because of complications RELATED TO CAPD, indicate the main reason for abandonment. Enter code from Instruction Sheet

223

For ALL patients

14. Record body weight to nearest kilogram (for example, record 56.4 kg as)
For patients on dialysis, record post dialysis weight

in December, 1984 or at time of death 224

15. Record body height to nearest centimetre (for example, record 161.5 cm as)

227

16. Has a parathyroidectomy been performed on this patient? Enter '1' for yes or '2' for no

230

If yes, give date of first parathyroidectomy 231

17. Malignancies (including reticulosos, leukaemias and malignancies diagnosed before dialysis/transplantation)

Record code from list corresponding to site of primary malignancy

236

Date of diagnosis

237

18. Record blood group of patient. Enter '1' for group AB, '2' for group A, '3' for group B and '4' for group O

241

FOR REGISTRY USE ONLY

242	246	250	254	258
262	266	270	274	278

INSTRUCTION SHEET FOR E.D.T.A. QUESTIONNAIRES, 1984

Patient Questionnaires

000729

1. Previously registered patients

All data previously reported on patients alive on treatment in your centre on 31st December 1983 has been pre-printed. Please update these questionnaires with data for 1984, and change any incorrect preprinted data in red ink but DO NOT delete any method of treatment or transfer recorded by previous centre(s).

2. New Patients

Blank questionnaires are enclosed for you to record data on patients who started treatment for end stage renal failure in 1984 or who came to your centre from another dialysis/transplant centre in 1984. Use blank questionnaires for any patient currently being treated in your centre but not shown in your patient listing. Additional blank questionnaires are available from the Registry on request.

3. Dead Patients

Patients previously reported as dead have been retained on our computer files for survival calculations etc., and do not need to be re-reported. These patients are shown in your patient listing.

Include all patients accepted for treatment for end stage renal failure and who have died.

Exclude patients treated for acute (reversible) renal failure or for poisoning or patients accepted for transient/holiday dialysis.

Transfer of Patients between Centres

Please return all forms direct to the Registry. If a patient has been transferred DO NOT send form to the other centre. Please read carefully the sections of this Instruction Sheet relating to questions 5 and 6. A list of codes for other dialysis/transplant centres in your country is enclosed.

Error Codes in Patients Reported Alive last Year

If erroneous or incomplete information has been recorded on the Registry files, the computer will print the following codes alongside the appropriate question:

???

Patient's initial treatment(s) not reported

Erroneous or incomplete information or omission in date, please correct.

If *** appears alongside an 'R' code in question 6, it indicates that the patient was reported as departure from your centre last year but transfer could not be processed due to inadequate address. This patient will be considered lost to follow up (category 8 in question 6) unless you give the complete address this year of the centre to which he/she was transferred in question 5b.

###

Non-consecutive date sequence, please correct.

Please use red ink to correct any errors

DEADLINE-15th FEBRUARY, 1985

Please complete and return the questionnaires by this date to:

Dr A.J. Wing
E.D.T.A. Registry
St. Thomas' Hospital
London SE1 7EH
United Kingdom

00	Chronic renal failure, aetiology uncertain	50	Hereditary/Familial nephropathy—type unspecified
10	Glomerulonephritis, histologically NOT examined	51	Hereditary nephritis with nerve deafness (Alport's Syndrome)
11	Severe nephrotic syndrome with focal sclerosis (paediatric patients only)	52	Cystinosis
12	IgA nephropathy (proven by immunofluorescence, not code 85)	53	Oxalosis
13	Dense deposit disease (proven by immunofluorescence and/or electron microscopy)	59	Hereditary nephropathy—other (specify if you wish)
19	Glomerulonephritis, histologically examined (specify if you wish)		
20	Pyelonephritis/Interstitial nephritis—cause not specified	60	Congenital renal hypoplasia—type unspecified
21	Pyelonephritis/Interstitial nephritis associated with neurogenic bladder	61	Oligomeganephronic hypoplasia
22	Pyelonephritis/Interstitial nephritis due to congenital obstructive uropathy with or without vesico-ureteric reflux	62	Segmental renal hypoplasia (Ask-Upmark kidney)
23	Pyelonephritis/Interstitial nephritis due to acquired obstructive uropathy (specify if you wish)	63	Congenital renal dysplasia with or without urinary tract malformation
24	Pyelonephritis/Interstitial nephritis due to vesico-ureteric reflux without obstruction	66	Syndrome of agenesis of abdominal muscles (Prune Belly Syndrome)
25	Pyelonephritis/Interstitial nephritis due to urolithiasis	70	Renal vascular disease—type unspecified
29	Pyelonephritis/Interstitial nephritis due to other cause (specify if you wish)	71	Renal vascular disease due to malignant hypertension (NO primary renal disease)
30	Nephropathy caused by drugs or nephrotoxic agents—cause not specified	72	Renal vascular disease due to hypertension (NO primary renal disease)
31	Nephropathy due to analgesic drugs	73	Renal vascular disease due to polyarteritis
39	Nephropathy caused by specific drug (specify if you wish)	74	Wegener's granulomatosis
40	Cystic kidney disease—type unspecified	79	Renal vascular disease—classified (specify if you wish)
41	Polycystic kidneys, adult type	80	Diabetes—insulin dependent (Type I)
42	Polycystic kidneys, infantile and juvenile types	81	Diabetes—non-insulin dependent (Type II)
43	Medullary cystic disease, including nephronophthisis	82	Myelomatosis
49	Cystic kidney disease—other specified type (specify if you wish)	83	Amyloid
50	Hereditary/Familial nephropathy—type unspecified	84	Lupus erythematosus
51	Hereditary nephritis with nerve deafness (Alport's Syndrome)	85	Henoch-Schönlein purpura
52	Cystinosis	86	Goodpasture's Syndrome
53	Oxalosis	87	Scleroderma
59	Hereditary nephropathy—other (specify if you wish)	88	Haemolytic Uræmic Syndrome (Moschowitz Syndrome)
		89	Multi-system disease—other (specify if you wish)
		90	Cortical or tubular necrosis
		91	Tuberculosis
		92	Gout
		93	Nephrocalcinosis and hypercalcaemic nephropathy
		94	Balkan nephropathy
		95	Kidney tumour
		96	Traumatic or surgical loss of kidney
		99	Other identified renal disorders—please specify
			(96 Preprinted by computer = Other identified renal disorder (nephropathy specified))

Give date _____

Enter centre code from enclosed address list. If the code is not available, please give complete address of other centre.

Question 6 Course of treatment and transfers.

Codes for Method of Treatment

- 1 Hospital haemodialysis or haemofiltration (includes limited care and training for home)
- 2 Home haemodialysis or haemofiltration (includes temporary transfer to hospital)
- 3 Intermittent peritoneal dialysis (IPD), hospital or home
- 4 Continuous peritoneal dialysis (CAPD, CCPD), hospital and home (includes temporary use of other methods of PD)

- 5 Transplantation (if 5 recorded, the next code should be 6 or 7)
- 6 Onset of function of transplanted kidney adequate to make dialysis unnecessary
- 7 Irreversible failure of transplanted kidney
- 8 Patient untraced (give date of last contact)
- 9 Patient recovered sufficient function of own kidneys to make dialysis unnecessary

Codes for transfers:

- T Patient CAME TO your centre from another dialysis/transplant centre. Do not use code 'T' for patients starting treatment for the first time. If you enter code 'T', this should be followed by code 1, 2, 3, 4, 5 or 6 as next 'change'.
- R Patient SENT FROM your centre to another dialysis/transplant centre. Code 'R' ends record of treatment in your centre. Do not enter any code after code 'R' unless patient CAME BACK to your centre when code 'T' should be entered with date of return and this should be followed by code 1, 2, 3, 4, 5 or 6 as next 'change'.

NOTE: All 'R' codes are removed when the complete treatment sequence for a patient is assembled by the Registry. Please do not change the preprinted 'T' code to 'R'. Only amend question 6 if a treatment or a transfer has been incorrectly reported.

Record of Treatment and Transfers concerning YOUR centre

Examples:



Example of patient who started first treatment (codes 1, 2, 3, 4 or 5) in your centre

Method of Treatment	Day	Month	Year	
3 1st Treatment	08	04	84	Started intermittent peritoneal dialysis 8 April 84
1 1st Change	11	04	84	Changed to hospital haemodialysis 11 April 84



Example of a patient who came from another dialysis/transplant centre for CAPD in your centre

T 1st Treatment	13	02	84	Patient came to your centre from another dialysis/transplant centre (also enter centre code and date in question 5 (a))
4 1st Change	13	02	84	Patient on continuous ambulatory peritoneal dialysis (includes temporary use of other methods of PD)
1 2nd Change	07	08	84	Changed to hospital haemodialysis
4 3rd Change	05	09	84	Returned to CAPD



Example of a patient who came to your centre for transplantation and was sent to another (or the original) centre with a functioning transplant

T 1st Treatment	21	01	84	Patient came to your centre from another dialysis/transplant centre (also enter centre code and date in question 5 (a))
5 1st Change	21	01	84	Transplantation
6 2nd Change	04	02	84	DO NOT RECORD TEMPORARY SUPPORTIVE DIALYSIS Transplant function adequate
R 3rd Change	15	05	84	Patient sent from your centre to another (or original) dialysis/transplant centre (also enter centre code and date in question 5(b))



Example of patient who started first treatment in your centre, was sent to another dialysis/transplant centre and returned to your centre for continuation of care with a functioning transplant

1 1st Treatment	16	02	84	Started hospital haemodialysis
R 1st Change	06	04	84	Patient sent from your centre to another dialysis/transplant centre (also enter centre code and date in question 5(b))
T 2nd Change	10	10	84	Patient returned to your centre from another dialysis/transplantation centre (also enter centre code and date in question 5(a))
6 3rd Change	10	10	84	Continued care of patient with adequate function of transplanted kidney DO NOT RECORD TEMPORARY SUPPORTIVE DIALYSIS
7 4th Change	12	11	84	Irreversible failure of transplanted kidney
1 5th Change	12	11	84	Returned to hospital haemodialysis



Complete question 7 for patients who have died

Question 7a If patient was not alive on 1st January 1985, give date of death

Question 7b Record code from list corresponding to main cause of death (if '99'—specify)

000732

00 Cause of death uncertain/not determined

Cardiac

- 11 Myocardial ischaemia and infarction
- 12 Hyperkalaemia
- 13 Haemorrhagic pericarditis
- 14 Other causes of cardiac failure
- 15 Cardiac arrest, cause unknown
- 16 Hypertensive cardiac failure
- 17 Hypokalaemia
- 18 Fluid overload

Vascular

- 21 Pulmonary embolus
- 22 Cerebro-vascular accident
- 23 Gastro-intestinal haemorrhage
- 24 Haemorrhage from graft site
- 25 Haemorrhage from vascular access or dialysis circuit
- 26 Haemorrhage from ruptured vascular aneurysm (not Code 22 or 23)
- 27 Haemorrhage from surgery (not Code 23, 24 or 26)
- 28 Other haemorrhage (not Codes 23—27)
- 29 Mesenteric infarction

Infection

- 31 Pulmonary infection (bacterial)
- 32 Pulmonary infection (viral)
- 33 Pulmonary infection (fungal)
- 34 Infections elsewhere (except viral hepatitis see 41)
- 35 Septicaemia
- 36 Tuberculosis (lung)
- 37 Tuberculosis (elsewhere)
- 38 Generalized viral infection
- 39 Peritonitis (not Code 70)

Liver Disease

- 41 Liver—due to hepatitis B virus
- 42 Liver—other viral hepatitis
- 43 Liver—drug toxicity
- 44 Cirrhosis—not viral
- 45 Cystic liver disease
- 46 Liver failure—cause unknown

Gastro-intestinal

- 23 Gastro-intestinal haemorrhage
- 29 Mesenteric infarction
- 62 Pancreatitis
- 70 Sclerosing (or adhesive) peritoneal disease
- 71 Perforation of peptic ulcer
- 72 Perforation of colon

Social

- 51 Patient refused further treatment
- 52 Suicide
- 53 Therapy ceased for any other reason

Miscellaneous

- 61 Uraemia caused by graft failure
- 62 Pancreatitis
- 63 Bone marrow depression
- 64 Cachexia
- 65 Unknown
- 66 Malignant disease possibly induced by immunosuppressive therapy
- 67 Malignant disease except those of 66
- 69 Dementia
- 70 Sclerosing (or adhesive) peritoneal disease
- 71 Perforation of peptic ulcer
- 72 Perforation of colon

Accident

- 81 Accident related to treatment
- 82 Accident unrelated to treatment
- 99 Other identified cause of death, please specify

Question 7c Was a transplanted kidney functioning up to time of death? If yes, record '1' in box, if no record '2'

Complete questions 8 and 9 for patients who have been transplanted

For question 8a, b and c record code number in box

Question 8a Source of donor kidney

- 1 Cadaver
- 2 Mother or father
- 3 Sister or brother—two shared haplotypes
- 4 Sister or brother—one shared haplotype
- 5 Sister or brother—no shared haplotypes
- 6 Sister or brother—genetic relationship unknown
- 7 Monozygotic (identical) twin
- 8 Other living related donor
- 9 Other living non-related donor

Question 8b Use of cyclosporin

- 1 Cyclosporin not used
- 2 Cyclosporin used at transplantation and use continued to 31st December, 1984, or graft failure or death
- 3 Cyclosporin used at transplantation but switched permanently to other immunosuppressive therapy up to 14 weeks following transplantation because of side effects
- 4 Cyclosporin used at transplantation but switched permanently to other immunosuppressive therapy after 14 weeks following transplantation because of side effects
- 5 Cyclosporin used at transplantation but switched permanently to other immunosuppressive therapy up to 14 weeks following transplantation due to planned protocol
- 6 Cyclosporin used at transplantation but switched permanently to other immunosuppressive therapy after 14 weeks and up to 28 weeks following transplantation due to planned protocol
- 7 Cyclosporin used at transplantation but switched permanently to other immunosuppressive therapy after 28 weeks following transplantation due to planned protocol
- 8 Other maintenance immunosuppressive therapy used at transplantation but switched to cyclosporin and continued cyclosporin to 31st December, 1984, or graft failure, or death
- 9 Transient (interrupted) use of cyclosporin (for example, for a rejection episode)

Question 8c Cause of graft failure

- 1 Hyperacute rejection (leading to failure within 48 hours of transplantation)
- 2 Rejection while taking immunosuppressive drug(s)
- 3 Rejection after stopping all immunosuppressive drug(s)
- 4 Recurrent primary renal disease
- 5 Vascular or ureteric operative problems (not code 6)
- 6 Vascular (arterial or venous) thrombosis not related to operative problems or rejection
- 7 Infection of graft
- 8 Removal of functioning graft
- 9 'Non-viable' kidney
- 0 Other (please specify alongside box)

Question 9 If the patient's graft was functioning in December, 1984, enter code for serum creatinine level at end of 1984.

- Record:
- '1' for 120 $\mu\text{mol/l}$ or less (1.35 mg%)
 - '2' for 121–160 $\mu\text{mol/l}$ (1.36–1.80 mg%)
 - '3' for 161–200 $\mu\text{mol/l}$ (1.81–2.25 mg%)
 - '4' for 201–240 $\mu\text{mol/l}$ (2.26–2.70 mg%)
 - '5' for 241–300 $\mu\text{mol/l}$ (2.71–3.40 mg%)
 - '6' for 301–400 $\mu\text{mol/l}$ (3.41–4.50 mg%)
 - '7' for more than 400 $\mu\text{mol/l}$ (4.50 mg%)

Complete questions 10 and 11 for patients on haemodialysis (HD) or haemofiltration (HF) AT ANY TIME DURING 1984

Question 10a Record in box the average number of TIMES per week the patient was treated by HD or HF

000733

Question 10b Record in box the average number of HOURS per week the patient was treated by HD or HF

Question 10c Record in box code from list corresponding to TYPE of haemodialyser or haemofilter most frequently used for this patient during the past 12 months. For list of dialysers and haemofilters see below and next page. (The name of haemodialyser or haemofilter, when quoted, has been given by the manufacturer.)

Question 10d Record in box the number of TIMES on average this haemodialyser or haemofilter was re-used. Enter '0' for no re-use, '1' for one re-use, '2' for two re-uses, etc... and '9' for nine or more times.

Question 11 Did this patient's weight gain between HD/HF treatments exceed 4 kilograms (or 8% of body weight for patients aged less than 15 years) at least once a week during 1984? Enter '1' for yes or '2' for no.

NON-DISPOSABLE PARALLEL-FLOW DIALYSER (KIIL TYPE)

101 Meltec	Micro-point 3 (Mini) 0.81 M ²	106 Meltec	Multi-point Midi 0.77 M ²
102 Meltec	Micro-point 3 (Midi) 0.77 M ²	107 Meltec	Multi-point Maxi 1.07 M ²
103 Meltec	Micro-point 3 1.02 M ²	108 Meltec	3 layer Midi-plus 1.15 M ²
104 Meltec	Multi-point Paediat. 0.5 M ²	109 Meltec	3 layer Maxi-plus 1.53 M ²
105 Meltec	Multi-point Mini 0.61 M ²	110 Other	Non-disposable parallel-flow dialyser

DISPOSABLE PARALLEL-FLOW DIALYSER

201 Bellco	Bravo BL 500 Low UF 1.1 M ²	244 Hospal	Biospal 3000 S AN 69 S 1.2 M ²
202 Bellco	Bravo BL 501 High UF 1.1 M ²	245 Hospal	Biospal 2400 S AN 69 S 1.0 M ²
203 Bellco	Bravo BL 512 Vary High UF 12 Micron 1.1 M ²	246 Hospal	Biospal 1800 S AN 69 S 0.7 M ²
204 Bellco	Bravo BL 504 High UF 1.4 M ²	247 Hospal	Biospal 1200 S AN 69 S 0.5 M ²
205 Colse	PPD Parallel plate 0.8 M ²	248 Hospal	Biospal S.C.U./C.A.V.H. Filter 0.5 M ²
206 Colse	PPD Parallel plate 1.3 M ²	249 Hospal	H12-10 AN 69 1.0 M ²
207 Colse	PPD Parallel plate 1.6 M ²	250 Hospal	H12-07 AN 69 0.7 M ²
208 Colse	PPD Parallel plate 1.9 M ²	251 Hospal	RP610 AN 69 1.0 M ² (as dialyser)
209 Extracorporeal	EXP 200 0.8 M ²	252 Hospal	RP607 AN 69 0.7 M ²
210 Extracorporeal	EXP 300 0.8 M ²	253 Hospal	RP6 AN 69 1.0 M ² —1-6 layers used
211 Extracorporeal	EXP 400 1.15 M ²	254 Hospal	—7-9 layers used
212 Extracorporeal	EXP 500 1.15 M ²	255 Hospal	(as dialyser) —10-12 layers used
213 Extracorporeal	EXP 600 1.45 M ²	256 Hospal	—13-16 (all) layers used
214 Extracorporeal	EXP 700 1.45 M ²	257 Hospal	H10-10 1.0 M ²
215 Extracorporeal	EX-85 1.2 M ²	258 Hospal	RP514 1.4 M ²
216 Gambro	Lundia Minor 0.54 M ²	259 Hospal	RP510 1.0 M ²
217 Gambro	Lundia Nova or Optime 13.5 micr. 1.0 M ²	260 Hospal	RP5 1.0 M ² —1-6 layers used
218 Gambro	Lundia Nova or Optime 17 micr. 1.0 M ²	261 Hospal	—7-9 layers used
219 Gambro	Lundia Major 1.5 M ²	262 Hospal	—10-12 layers used
220 Gambro	GL Mini Minor 13.5 Micron 0.23 M ²	263 Hospal	—13-16 (all) layers used
221 Gambro	GL Minor 13.5 Micron 0.41 M ²	264 Medical	IsoNephros TM Optimum 1.0 M ²
222 Gambro	GLP 11.5 Micron 1.0 M ²	265 Nikkiso	ND-12 1.2 M ²
223 Gambro	GLP 11.5 Micron M 1.0 M ²	266 Nikkiso	ND-14 1.4 M ²
224 Gambro	GLP 11.5 Micron H 1.0 M ²	267 Nikkiso	NDF-12 1.2 M ²
225 Gambro	GLP 17 Micron 1.0 M ²	268 Organon Teknika	Nephros Piccolo Plate 0.8 M ²
226 Gambro	GLM 11.5 Micron 1.36 M ²	269 Organon Teknika	Nephros Lento Plate 1.3 M ²
227 Gambro	GLM 11.5 Micron H 1.36 M ²	270 Organon Teknika	Nephros Andante Plate 1.6 M ²
228 Gambro	GLM 17 Micron 1.36 M ²	271 Organon Teknika	Nephros Allegro Plate 1.9 M ²
229 Gambro	GLP High Flux 0.95 M ² (as dialyser)	272 Secon	132 MTL-Technic 0.85 M ²
230 Gambro	GLM High Flux 1.36 M ² (as dialyser)	273 Secon	133 MTL-Technic 0.85 M ²
231 Gambro	GL Ultraflux 1.8 M ² (as dialyser)	274 Secon	103 MTL-Technic 0.76 M ²
232 Gambro	Lundia 10-1N 0.4 M ²	275 Secon	104 MTL-Technic 1.35 M ²
233 Gambro	Lundia 10-1H 0.4 M ²	276 Secon	105 MTL-Technic 1.35 M ²
234 Gambro	Lundia 10-2L 0.6 M ²	277 Secon	235 Haemodiafilter 1.25 M ²
235 Gambro	Lundia 10-2N 0.8 M ²	278 Secon	H.D. 58 0.64 M ²
236 Gambro	Lundia 10-3L 0.8 M ²	280 Travencol	H.D. S10 0.92 M ²
237 Gambro	Lundia 10-3N 0.8 M ²	281 Travencol	H.D. S11 0.92 M ²
238 Gambro	Lundia 10-3H 0.8 M ²	282 Travencol	H.D. 1000 0.92 M ²
241 Gambro	Lundia 10-SL 1.1 M ²	283 Travencol	H.D. 1001 0.92 M ²
242 Gambro	Lundia 10-SN 1.1 M ²	284 Travencol	H.D. 1401 1.39 M ²
243 Gambro	Lundia 10-SH 1.1 M ²	285 Travencol	
		287 Other	Disposable parallel-flow dialyser

DISPOSABLE COIL DIALYSER

301 Bellco	Vita 2 low UF 1.0 M ²	315 Kohinoor	Coil Cuprophen 1.0 M ²
302 Bellco	Vita 2 high UF 1.0 M ²	316 Kohinoor	Coil Nephrophen 1.0 M ²
303 Bellco	Standard UF 1.2 M ²	317 Sorin	ALT 77 A 0.66 M ²
304 Extracorporeal	EX-20 0.3 M ²	318 Sorin	ALT 77 0.78 M ²
305 Extracorporeal	EX-01 0.7 M ²	319 Sorin	ALT 100 A 0.91 M ²
306 Extracorporeal	EX-21 0.7 M ²	320 Sorin	ALT 100 1.06 M ²
307 Extracorporeal	EX-23 0.8 M ²	321 Sorin	ALT 140 1.4 M ²
308 Extracorporeal	EX-03 0.84 M ²	322 Sorin	ALT 140 Low (low ultrafiltration) 1.24 M ²
309 Extracorporeal	EX-25 1.0 M ²	323 Travencol	CD Standard Dialyser 0.9 M ²
310 Extracorporeal	EX-26 1.4 M ²	325 Travencol	CD 1400 1.4 M ²
311 Gambro	GLC 1.0 M ²	326 Travencol	Ultra Flo II Standard 100 1.0 M ²
312 Gambro	GLC 1.2 M ²	328 Other	Disposable coil dialyser
313 Hospal	Decco Dialix SF 1062/2062/3062/ 1.0 M ²		

CAPILLARY DIALYSER (HOLLOW FIBRE)

401 Asahi	AM-03 0.3 M ²	478 Nipro	C-110 11 Micron 1.1 M ²
402 Asahi	AM-06 0.6 M ²	479 Nipro	C-130 11 Micron 1.3 M ²
403 Asahi	AM-10L 1.1 M ²	480 Nipro	C-150 1.5 M ²
404 Asahi	AM-10 1.1 M ²	481 Nipro	C-180 11 Micron 1.8 M ²
405 Asahi	AM-10H 1.1 M ²	482 Nipro	NF-01 1.05 M ²
406 Asahi	AM-20L 1.6 M ²	483 Nipro	NF-01-L 1.25 M ²
407 Asahi	AM-20 1.6 M ²	484 Nipro	NF-02 1.7 M ²
408 Asahi	AM-30L 2.1 M ²	485 Nipro	NF-01-L C-130 1.3 M ²
409 Asahi	AM-30 2.1 M ²	486 Nipro	NF-01-L C-150 1.5 M ²
410 Asahi	NR-100 1.0 M ²	487 Organon Teknika	Nephross 11F 100 1.0 M ²
411 Asahi	NR-150 1.5 M ²	488 Organon Teknika	Nephross 16F 160 1.6 Micron 1.6 M ²
412 Asahi	AM-710	489 Organon Teknika	Nephross Lento H.F. 11 Micron 0.7 M ²
413 Asahi	AM-720	490 Organon Teknika	Nephross Andante H.F. 8 Micron 0.8 M ²
414 Asahi	AM-730	491 Organon Teknika	Nephross Andante 11 Micron 1.0 M ²
415 Asahi	PAN-150 (as dialyser)	492 Organon Teknika	Nephross Allegro 11 Micron 1.4 M ²
416 Asahi	PAN-200 (as dialyser)	493 Organon Teknika	Nephross Presto 11 Micron 1.7 M ²
417 Asahi	PAN-250 (as dialyser)	494 Salvia	KF 1 0.8 M ²
418 Asahi	AM-100L	495 Salvia	KF 1 1.0 M ²
419 Asahi	AM-100M	496 Salvia	KF 1 1.2 M ²
420 Asahi	AM-100H	497 Salvia	KF 1 1.5 M ²
421 Asahi	AM-150L	498 Salvia	KF 101 EVAL 1.3 M ²
422 Asahi	AM-150M	499 Salvia	Renak-E 0.8 L 0.8 M ²
423 Asahi	AM-150H	500 Salvia	Renak-E 0.8 M 0.8 M ²
424 Asahi	AM-200L	501 Salvia	Renak-E 1.2 M 1.2 M ²
425 Asahi	AM-200M	502 Salvia	Renak-E 1.2 H 1.2 M ²
426 Asahi	AM-200H	503 Salvia	Renak-E 1.5 M 1.5 M ²
427 Asahi	AM-300L	504 Salvia	Renak-E 1.5 H 1.5 M ²
428 Asahi	AM-300M	577 Secon	S 119 ETO 1.0 M ²
429 Asahi	AM-300H	578 Secon	S 119 Gamma 1.0 M ²
430 Bellico	Prima BL 611-L 16 micron 1.1 M ²	579 Secon	S 120 ETO 1.0 M ²
431 Bellico	Prima BL 612-M 11 Micron 1.2 M ²	580 Secon	S 120 Gamma 1.0 M ²
432 Bellico	Prima BL 613-H 8 micron 1.3 M ²	581 Secon	S 121 ETO 1.2 M ²
433 Bellico	Tecno 50 C 16 micron 1.2 M ²	582 Secon	S 121 Gamma 1.2 M ²
434 Bellico	Tecno 50 C 16 micron 1.5 M ²	583 Secon	S 122 ETO 1.2 M ²
435 Bellico	C-DAK 1.3 M ²	584 Secon	S 122 Gamma 1.2 M ²
436 CD Medical/MLW	C-DAK 1.8 M ²	585 Secon	S 123 ETO 1.4 M ²
437 CD Medical	C-DAK 2.5 M ²	586 Secon	S 123 Gamma 1.4 M ²
438 CD Medical	C-DAK 3500 0.9 M ²	587 Secon	S 124 ETO 1.4 M ²
439 CD Medical	C-DAK 3500 'HP' 0.9 M ²	588 Secon	S 124 Gamma 1.4 M ²
440 CD Medical	C-DAK 4000 1.4 M ²	508 S.M.A.D.	MP 100-1 1.0 M ²
441 CD Medical	C-DAK 4000 'HP' 1.4 M ²	509 S.M.A.D.	MP 100-2 1.0 M ²
442 CD Medical	C-DAK 70 SCE 0.9 M ²	510 S.M.A.D.	MP 125 1.25 M ²
443 CD Medical	C-DAK 80 SCE 1.1 M ²	511 S.M.A.D.	MP 140 1.4 M ²
444 CD Medical	C-DAK 135 SCE 1.35 M ²	512 S.M.A.D.	GL 9 0.9 M ²
445 CD Medical	C-DAK Duo Flux 1.4 M ²	513 S.M.A.D.	GL 10 1.0 M ²
446 Cobe	H.F. 70 0.7 M ²	514 S.M.A.D.	GL 12 1.2 M ²
447 Cobe	H.F. 100 8 micron 0.8 M ²	515 S.M.A.D.	GL 14 1.4 M ²
448 Cobe	H.F. 130 1.2 M ²	516 S.M.A.D.	GL 16 1.6 M ²
449 Cobe	H.F. 140 1.4 M ²	517 Sorin	Spiralflow SD1 1.3 M ²
450 Erika	PCS A-10 0.7 M ²	518 Sorin	Spiralflow SD2 1.0 M ²
451 Erika	PCS B-10 0.8 M ²	519 Sorin	Spiralflow SD 811—8µ—1.11 M ²
452 Erika	PCS C-10 1.1 M ²	520 Sorin	Spiralflow SD 816—8µ—1.47 M ²
453 Extracorporeal	HPF-50 0.6 M ²	521 Sorin	Spiralflow SF 0.6 0.61 M ²
454 Extracorporeal	TriEx 1.0 M ²	522 Sorin	Spiralflow SF 0.8 0.83 M ²
455 Extracorporeal	TriEx 2.1 M ²	523 Sorin	Spiralflow SF 1.0 1.05 M ²
456 Extracorporeal	TriEx 3.1 M ²	524 Sorin	Spiralflow SF 1.3 1.32 M ²
457 Fresenius/Diade	Hemoflow 0.8 M ²	525 Sorin	Spiralflow SF 1.5 1.48 M ²
458 Fresenius/Diade	Hemoflow 1.0 M ²	526 Sorin	Spiralflow NT 1011 0.96 M ²
459 Fresenius/Diade	Hemoflow 1.3 M ²	527 Sorin	Spiralflow NT 1311 1.20 M ²
460 Fresenius/Diade	Hemoflow D1 0.6 M ²	528 Sorin	Spiralflow NT 1108 0.86 M ²
461 Fresenius/Diade	Hemoflow D1.5 0.8 M ²	529 Sorin	Spiralflow NT 1508 1.35 M ²
462 Fresenius/Diade	Hemoflow D2 1.1 M ²	530 Sorin	Spiralflow HF 080 0.80 M ²
463 Fresenius/Diade	Hemoflow D3 1.6 M ²	531 Sorin	Spiralflow HF 120 1.20 M ²
464 Fresenius/Diade	Hemoflow D6 2.0 M ²	532 Sorin	TH13 1.3 M ²
465 Fresenius/Diade	Hemoflow D8 2.8 M ²	533 Sorin	TH15 1.5 M ²
466 Fresenius/Diade	Hemoflow F40 0.65 M ²	534 Sorin	TE07 0.7 M ²
467 Fresenius/Diade	Hemoflow F80 1.25 M ²	535 Toray	TE10 1.0 M ²
468 Gambro	GF-80-M 0.9 M ²	536 Toray	TE12 1.2 M ²
469 Gambro	GF-80-H 0.9 M ²	537 Toray	TE15 1.5 M ²
470 Gambro	GF-120-L 1.1 M ²	538 Toray	Filtrayser B1 1.15 M ²
471 Gambro	GF-120-M 1.2 M ²	539 Toray	Filtrayser B1-70 0.75 M ²
472 Gambro	GF-120-ME 1.2 M ²	540 Toray	Filtrayser B1-90 0.95 M ²
473 Gambro	GF-120-H 1.2 M ²	541 Toray	Filtrayser B1-100 1.21 M ²
474 Gambro	GF-180-L 1.7 M ²	542 Toray	Filtrayser B1-150 1.21 M ²
475 Gambro	GF-180-M 1.8 M ²	543 Toray	Filtrayser B1-200 1.56 M ²
476 Gambro	GF-180-H 1.8 M ²	544 Toray	Filtrayser B1-M 1.36 M ²
477 Gambro	Disacap 140 1.4 M ²	545 Toray	Filtrayser B1-L 2.1 M ² (as dialyser)
	Disacap 110 1.0 M ²	546 Toray	Filtrayser B2-75 0.75 M ²
	Disacap 80 0.8 M ²	547 Toray	Filtrayser B2-95 0.95 M ²
	AL-110 1.1 M ²	548 Toray	Filtrayser B2-100 1.21 M ²
	AL-130 1.3 M ²	549 Toray	Filtrayser B2-150 1.21 M ²
	AL-110 G 1.1 M ²	550 Toray	Filtrayser B2-200 1.56 M ²
	AL-130 G 1.3 M ²	551 Travenol	Filtrayser B2-1.8 1.8 M ²
	ALC-10 1.0 M ²	552 Travenol	Filtrayser B2-300 2.05 M ²
	ALC-12 1.2 M ²	553 Travenol	Filtrayser B2-M 1.36 M ²
	ALC-18 1.8 M ²	554 Travenol	CF1211L 0.8 M ²
	ALF-12 1.2 M ²	555 Travenol	CF1211 0.8 M ²
	ALF-15 1.5 M ²	556 Travenol	CF1511 1.1 M ²
	ALF-08 0.8 M ²	557 Travenol	CF2308 1.24 M ²
	ALF-10 1.0 M ²	558 Travenol	CF1200 1.2 M ²
	D-90 H 8 Micron 0.9 M ²	559 Travenol	CF1500 1.5 M ²
	F-110 8 Micron 1.1 M ²	560 Travenol	CF2300 2.3 M ²
		561 Travenol	CA 130 1.3 M ²
		562 Travenol	CA 170 1.7 M ²
		563 Travenol	Capillary dialyser

OTHER TYPES OF DIALYSERS

601 Other Dialysers not listed

EQUIPMENT USED FOR HAEMOFILTRATION*

F01 Amicon	Diafilter [®] 20 0.2 M ²	F16 Gambro	FH 303 1.6 M ²
F02 Amicon	Diafilter [®] 30 0.5 M ²	F17 Hospal	Filtral AN89 1.0 M ²
F03 Amicon	Diafilter [®] 40 1.1 M ²	F18 Hospal	RP 610 AN89 1.0 M ² (as haemofilter)
F04 Amicon	Diafilter [®] 50 0.5 M ²	F19 Hospal	RP 6 AN89 1.0 M ² (as haemofilter)
F28 Asahi	PAN-50P	F20 Sartorius	SM 40004 0.6 M ²
F05 Asahi	PAN-150 (as haemofilter)	F21 Sartorius	SM 40041 0.4 M ²
F06 Asahi	PAN-200 (as haemofilter)	F22 Sartorius	SM 40042 0.6 M ²
F07 Asahi	PAN-250 (as haemofilter)	F23 Sartorius	SM 40043 1.0 M ²
F08 Gambro	GLP High Flux 0.95 M ² (as haemofilter)	F24 Secon	231 0.45 M ²
F10 Gambro	GLM High Flux 1.36 M ² (as haemofilter)	F25 Secon	232 0.75 M ²
F11 Gambro	GL Ultraflux 1.8 M ² (as haemofilter)	F26 Secon	233 0.9 M ²
F14 Gambro	FH 101 0.65 M ²	F27 Secon	234 0.9 M ²
F16 Gambro	FH 302 1.2 M ²	F28 Toray	Filtrayser B1-L 2.1 M ² (as haemofilter)
		F30 Other	Haemofilter or dialyser used as haemofilter

*Note: The term haemofiltration is restricted to treatment by a haemofilter without dialysis fluid and with replacement of ultrafiltrate by a substitution fluid.

Complete questions 12 and 13 for patients on continuous ambulatory peritoneal dialysis (CAPD) AT ANY TIME DURING 1984

Question 12 Record the number of episodes of peritonitis that occurred in this patient while treated by CAPD during 1984. If none, enter '00'

Question 13 If this patient abandoned CAPD during 1984 because of complications related to CAPD, enter code for the main reason for abandonment.

- 1 Peritonitis
- 2 Other abdominal complications
- 3 Inadequate dialysis (including inadequate ultrafiltration)
- 4 Patient unable to cope with CAPD
- 5 Patient's request
- 6 Family's request
- 7 Deep venous thrombosis (leg and/or pelvic)
- 8 Other complication related to CAPD

Complete questions 14 to 18 for ALL patients

Question 14 Record body weight to nearest kilogram (for example, record 56.4 kg as 056)
For patients on dialysis, record post dialysis weight
in December, 1984 or at time of death

Question 15 Record body height to nearest centimetre (for example, record 161.5 cm as 162)
Height reported last year (if known) will be preprinted

Question 16 Has a parathyroidectomy been performed on this patient? Enter '1' for yes or '2' for no.
If yes, give date of first parathyroidectomy (month, year)

Question 17 Malignancies (including reticuloses, leukaemias and malignancies diagnosed before dialysis/transplantation).

Record code from list corresponding to site of primary malignancy

- | | |
|--------------------------------------|---|
| 00 No malignancy diagnosed | |
| 11 More than one primary malignancy | |
| Skin (excluding lip and genital) | Neck and Thorax |
| 20 Squamous cell carcinoma | 53 Larynx |
| 21 Basal cell carcinoma | 54 Thyroid |
| 22 Squamous and basal cell carcinoma | 55 Bronchus |
| 23 Malignant melanoma | 56 Lung, primary tumour |
| Leukaemias and reticuloses | Urogenital tract |
| 25 Myeloma | 60 Kidney - Wilm's tumour |
| 26 Acute leukaemia | 61 Kidney - hypernephroma of host kidney |
| 27 Chronic leukaemia | 62 Kidney - hypernephroma of graft kidney |
| 29 Reticulum cell sarcoma | 63 Renal pelvis |
| 30 Kaposi's sarcoma | 64 Ureter |
| 31 Lymphosarcoma | 65 Urinary bladder |
| 33 Plasma cell lymphoma | 66 Urethra |
| 34 Hodgkin's disease | 67 Prostate |
| 35 Lymphoreticular tumour | 68 Testis |
| 36 Histiocytic reticulosis | 69 Penis |
| Gastro-intestinal tract | 70 Scrotum |
| 40 Lip | 71 Perineum |
| 41 Tongue | 72 Vulva |
| 42 Parotid | 73 Vagina |
| 43 Oesophagus | 74 Uterus - Cervix |
| 44 Stomach | 75 Uterus - Body |
| 45 Colon | 76 Ovary |
| 46 Rectum | |
| 47 Anus | Miscellaneous |
| 48 Liver - primary hepatoma | 80 Breast |
| 49 Liver - primary lymphoma | 81 Muscle |
| 50 Gall bladder and bile duct | 82 Bone |
| 51 Pancreas | 83 Brain - primary lymphoma |
| | 84 Brain - other primary tumour |
| | 85 Other tumour of central nervous system |
| | 90 Metastatic carcinoma, primary site unknown |
| | 99 Other primary tumour |

Date of diagnosis (month, year)

Question 18 Record blood group of the patient. Enter '1' for group AB, '2' for group A, '3' for group B and '4' for group O.